[Volume III, Appx00608 – Appx00880]

Nos. 22-2069, -2070, -2071, -2072

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,

Appellant,

v.

APPLE INC.,

Appellee.

APPEAL FROM THE PATENT TRIAL AND APPEAL BOARD
CASE NOS. IPR2021-00193, IPR2021-00195, IPR2021-00208, IPR2021-00209

JOINT APPENDIX

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(12) **United States Patent**
Poeze et al.

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(45) **Date of Patent: *Aug. 13, 2019**

(54) **MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS**

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This patent is subject to a terminal disclaimer.

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(58) **Field of Classification Search**
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(Continued)

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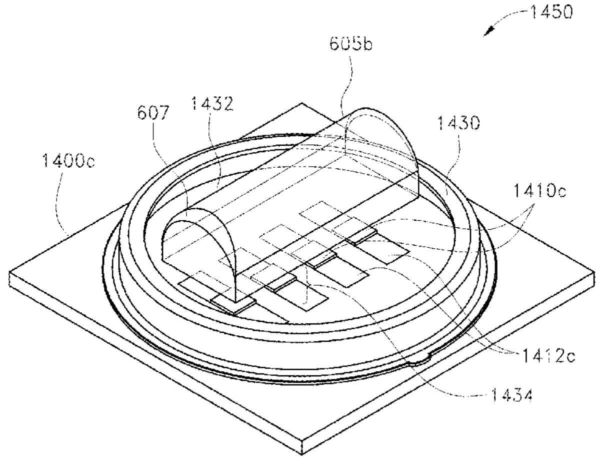
(57) **ABSTRACT**

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially linear substantially equal spaced geometry, a substantially linear substantially non-equal spaced geometry, and a substantially grid geometry.

19 Claims, 65 Drawing Sheets



Related U.S. Application Data

continuation of application No. 16/212,537, filed on Dec. 6, 2018, now Pat. No. 10,258,266, which is a continuation of application No. 14/981,290, filed on Dec. 28, 2015, now Pat. No. 10,335,068, which is a continuation of application No. 12/829,352, filed on Jul. 1, 2010, now Pat. No. 9,277,880, which is a continuation of application No. 12/534,827, filed on Aug. 3, 2009, and a continuation-in-part of application No. 12/497,528, filed on Jul. 2, 2009, now Pat. No. 8,577,431, which is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516, said application No. 12/829,352 is a continuation-in-part of application No. 12/497,523, filed on Jul. 2, 2009, now Pat. No. 8,437,825, which is a continuation-in-part of application No. 29/323,408, said application No. 12/497, 523 is a continuation-in-part of application No. 29/323,409.

(60) Provisional application No. 61/086,060, filed on Aug. 4, 2008, provisional application No. 61/086,108, filed on Aug. 4, 2008, provisional application No. 61/086,063, filed on Aug. 4, 2008, provisional application No. 61/086,057, filed on Aug. 4, 2008, provisional application No. 61/091,732, filed on Aug. 25, 2008, provisional application No. 61/078,228, filed on Jul. 3, 2008, provisional application No. 61/078,207, filed on Jul. 3, 2008.

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See application file for complete search history.

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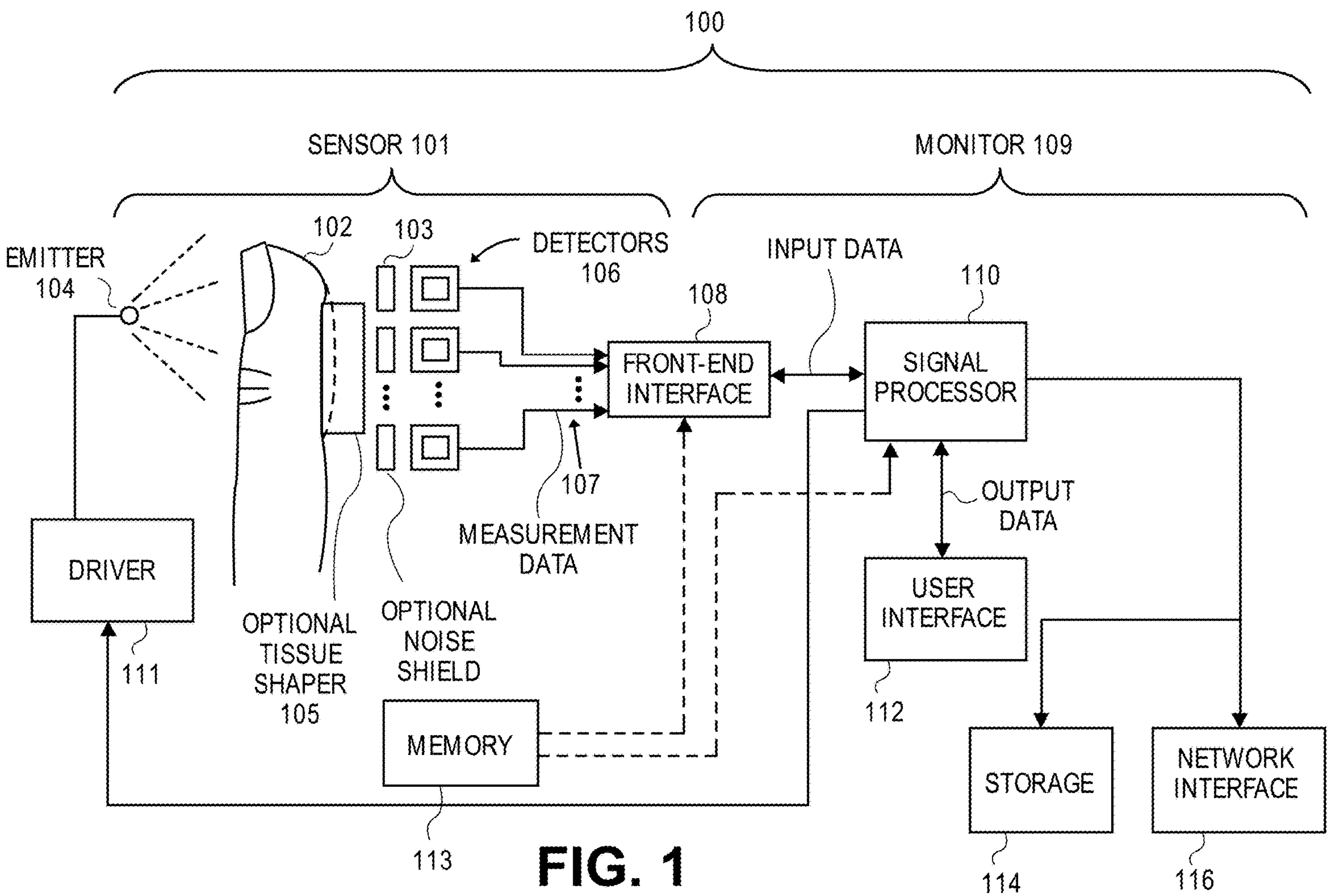

100
SENSOR 101
MONITOR 109
EMITTER 104
102
103
DETECTORS 106
INPUT DATA
110
108
FRONT-END INTERFACE
SIGNAL PROCESSOR
107
MEASUREMENT DATA
OUTPUT DATA
DRIVER
USER INTERFACE
OPTIONAL TISSUE SHAPER 105
OPTIONAL NOISE SHIELD
111
112
MEMORY
STORAGE
NETWORK INTERFACE
113
114
116

FIG. 1

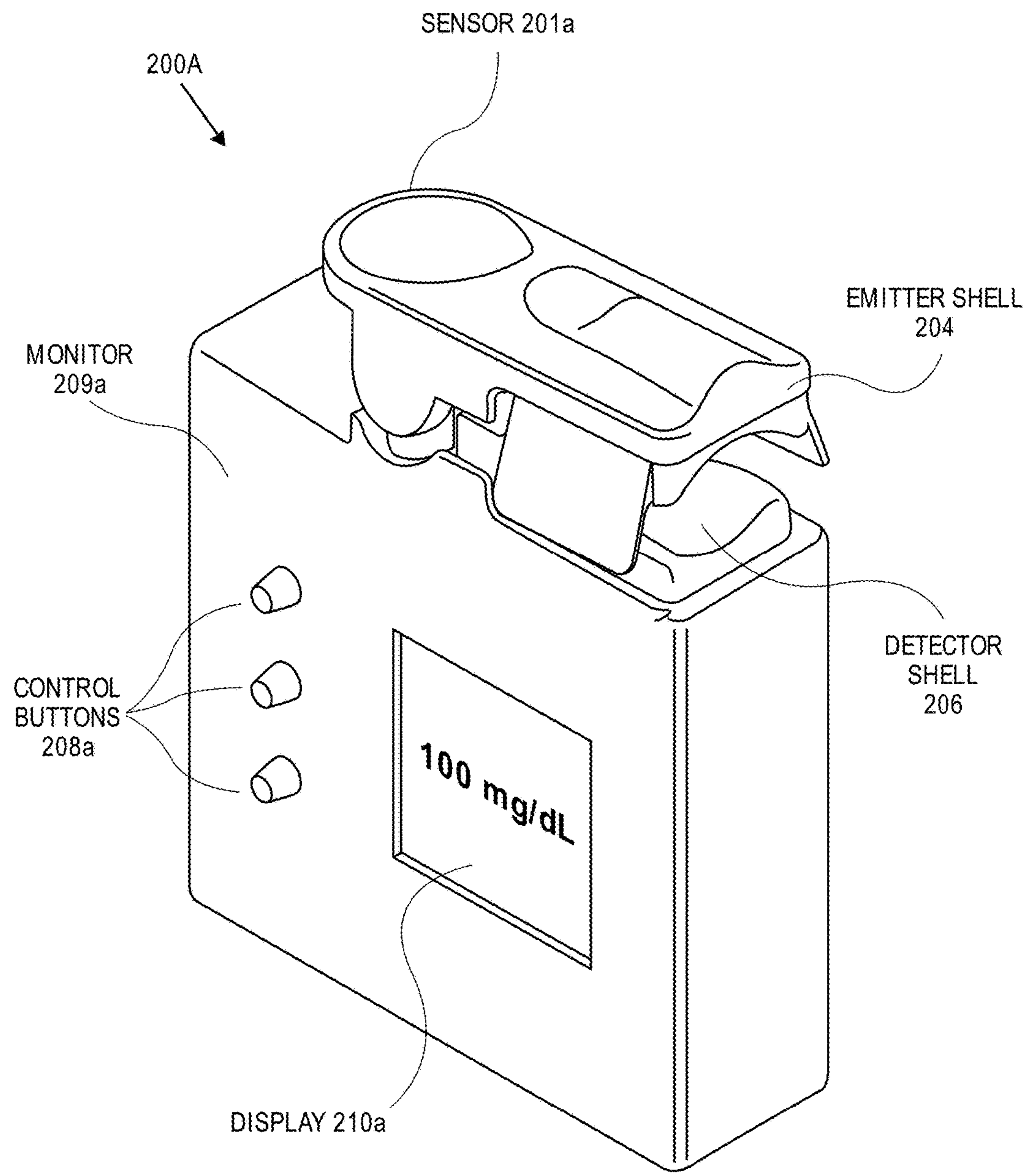
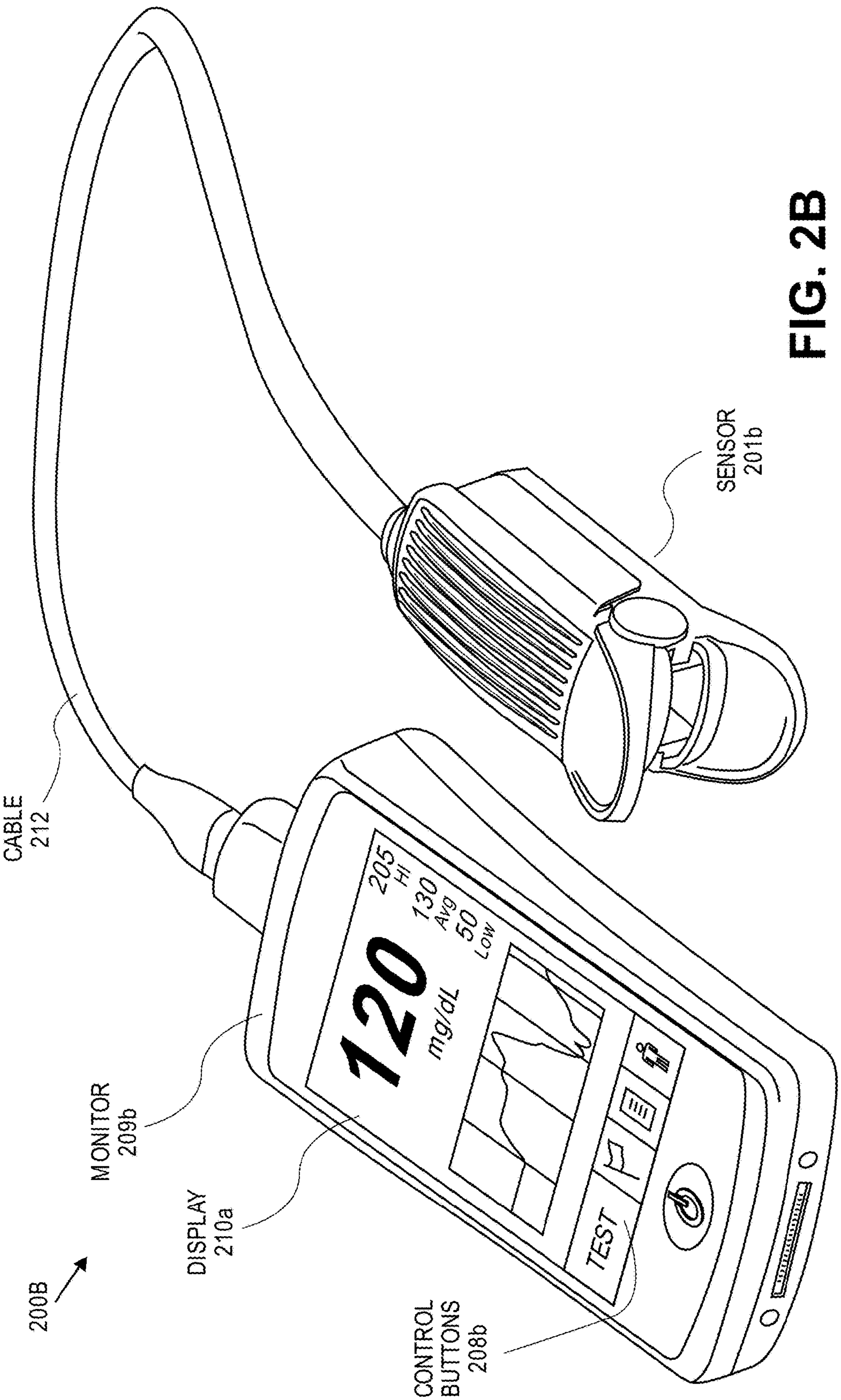

SENSOR 201a
200A
EMITTER SHELL 204
MONITOR 209a
DETECTOR SHELL 206
CONTROL BUTTONS 208a
100 mg/dL
DISPLAY 210a

FIG. 2A



200B
CABLE 212
MONITOR 209b
DISPLAY 210a
CONTROL BUTTONS 208b
SENSOR 201b
120 mg/dL
205 HI
130 Avg
50 Low
TEST

FIG. 2B

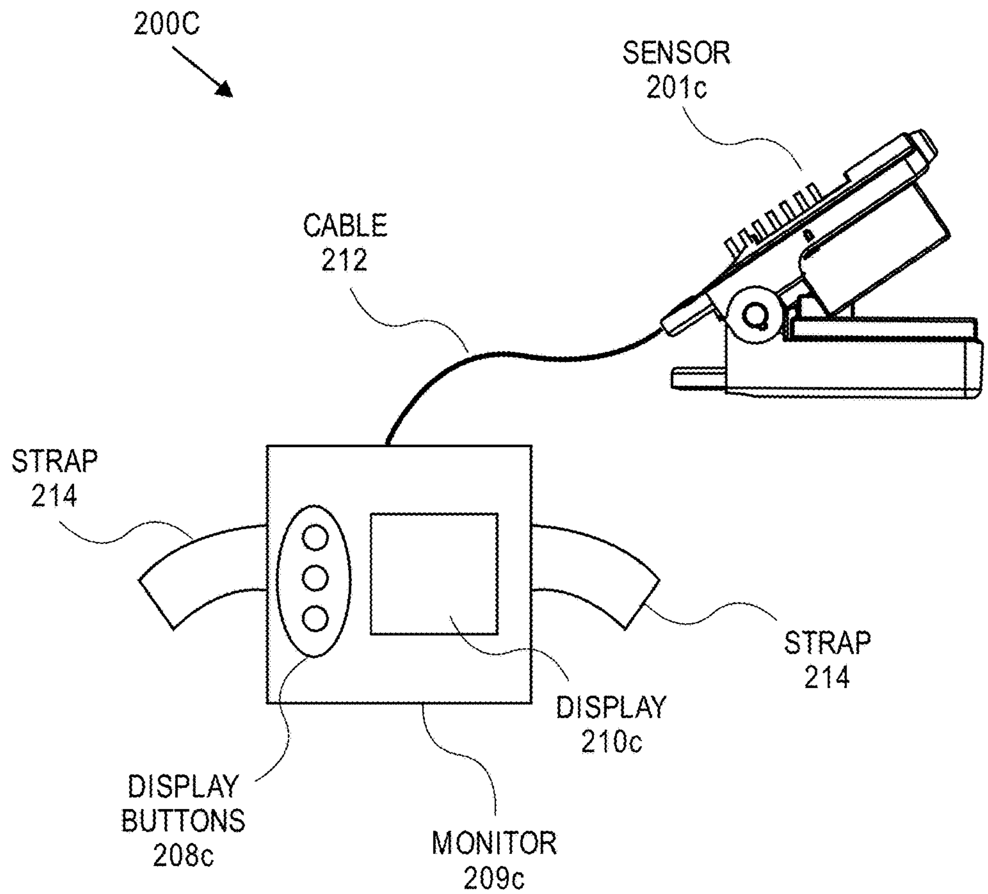

200C
SENSOR
201c
CABLE
212
STRAP
214
STRAP
214
DISPLAY
210c
DISPLAY
BUTTONS
208c
MONITOR
209c

FIG. 2C

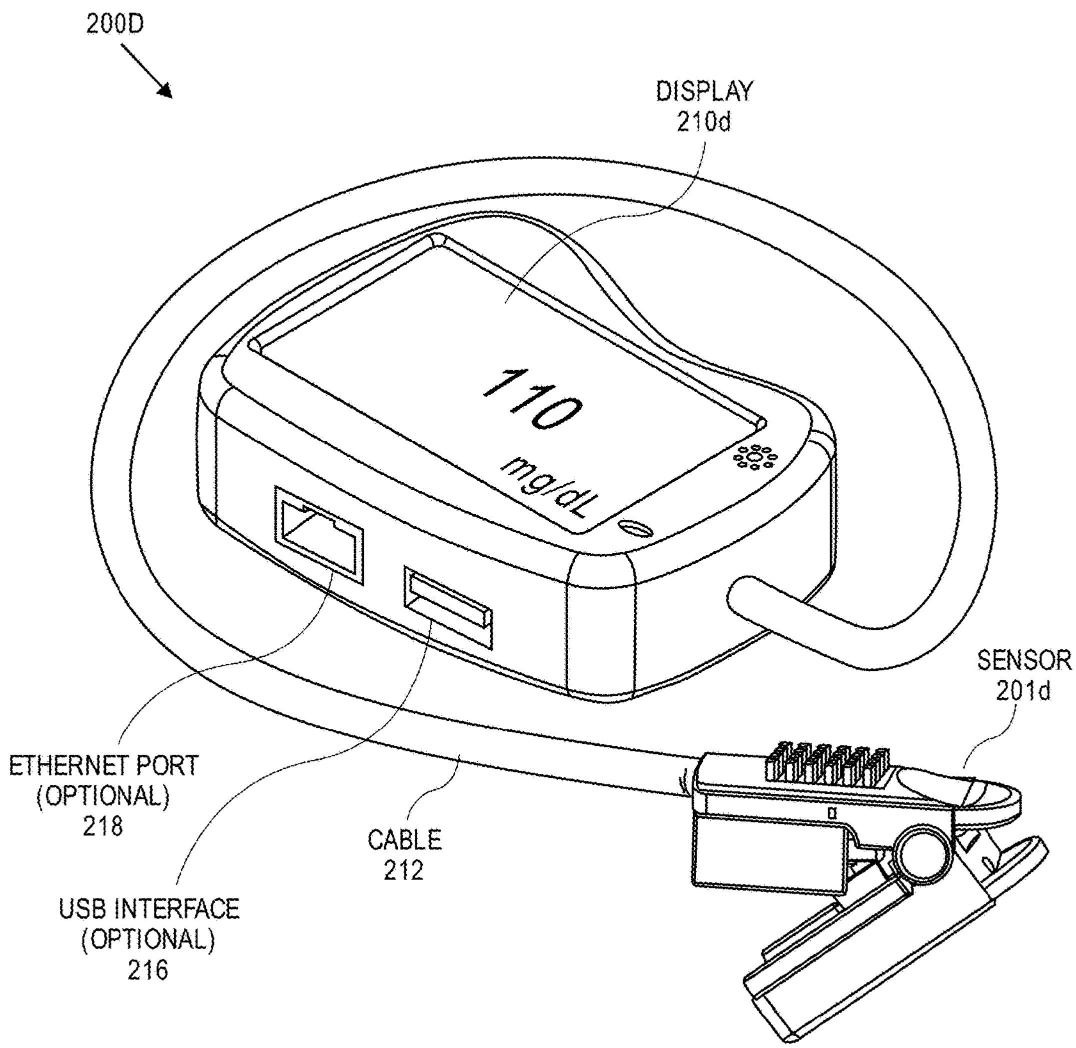

200D
DISPLAY
210d
110
mg/dL
SENSOR
201d
ETHERNET PORT
(OPTIONAL)
218
CABLE
212
USB INTERFACE
(OPTIONAL)
216

FIG. 2D

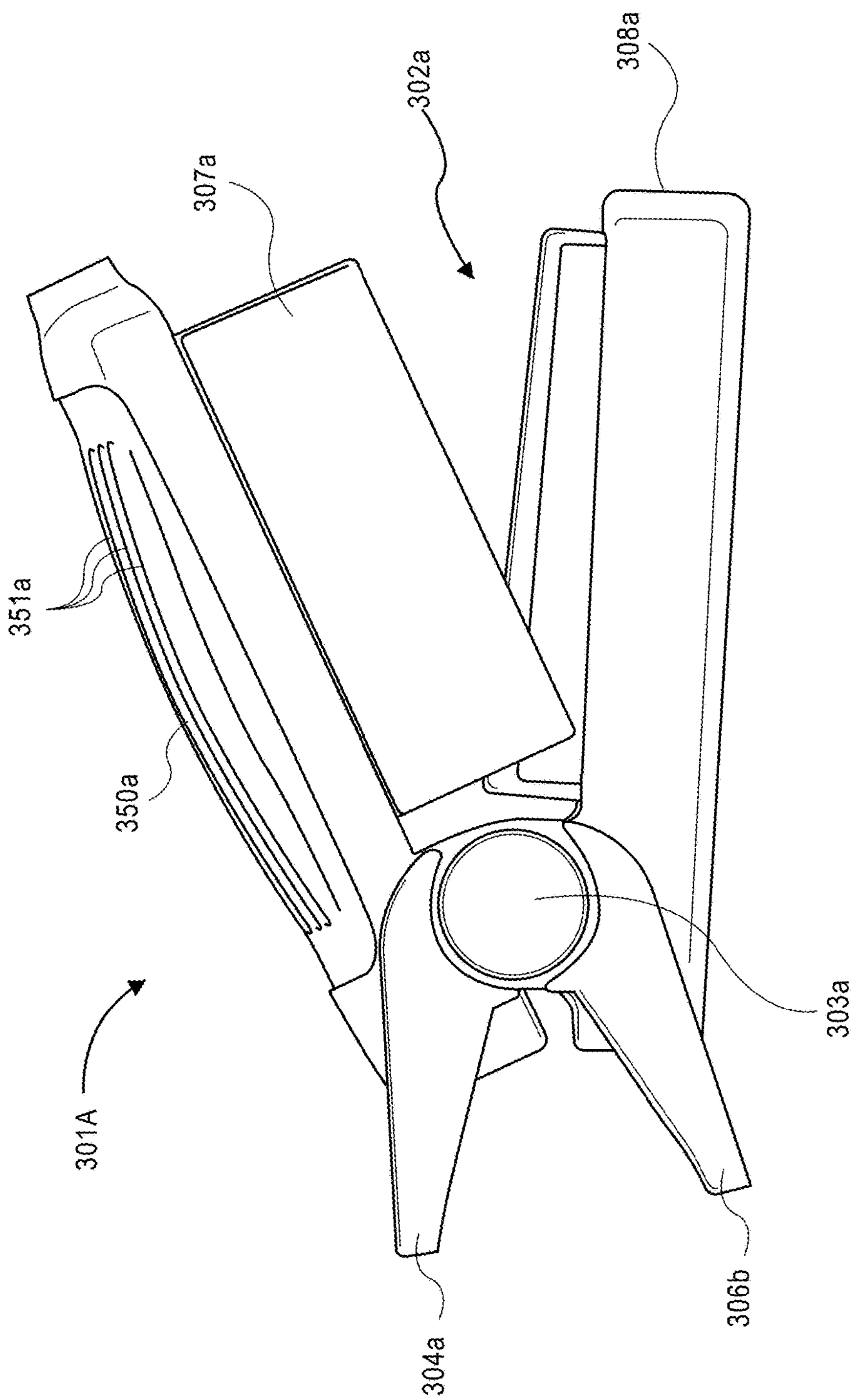


FIG. 3A

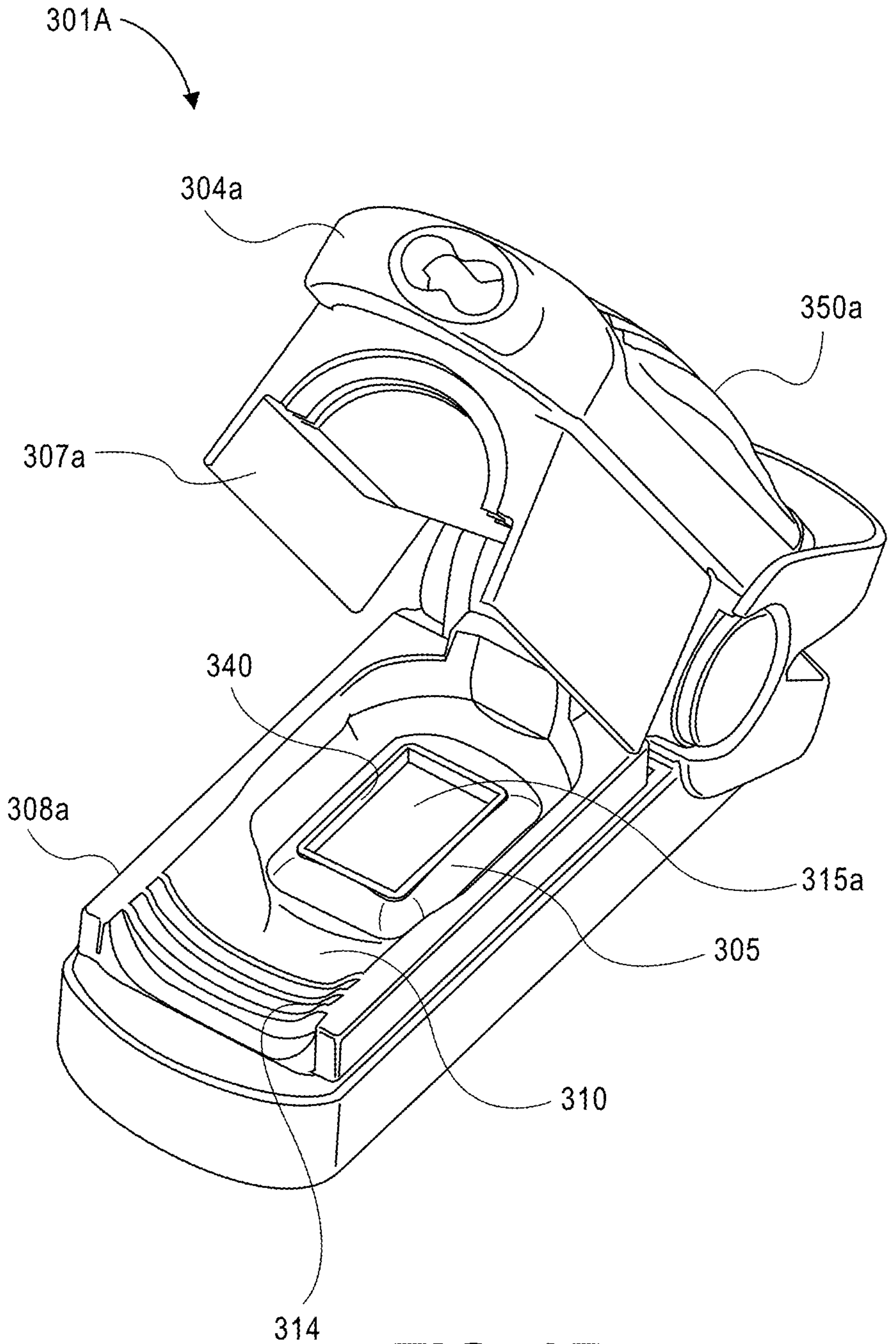


FIG. 3B

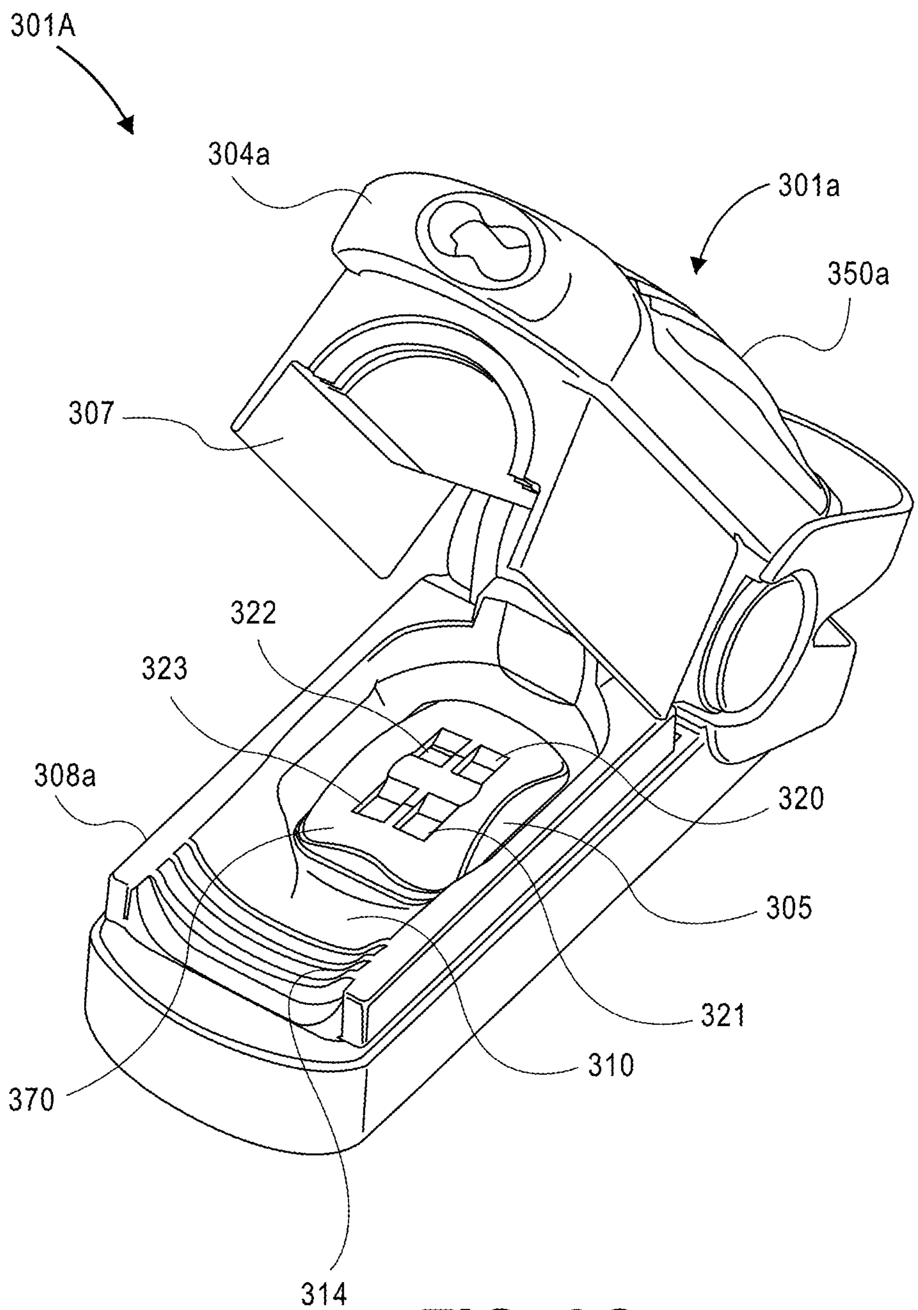


FIG. 3C

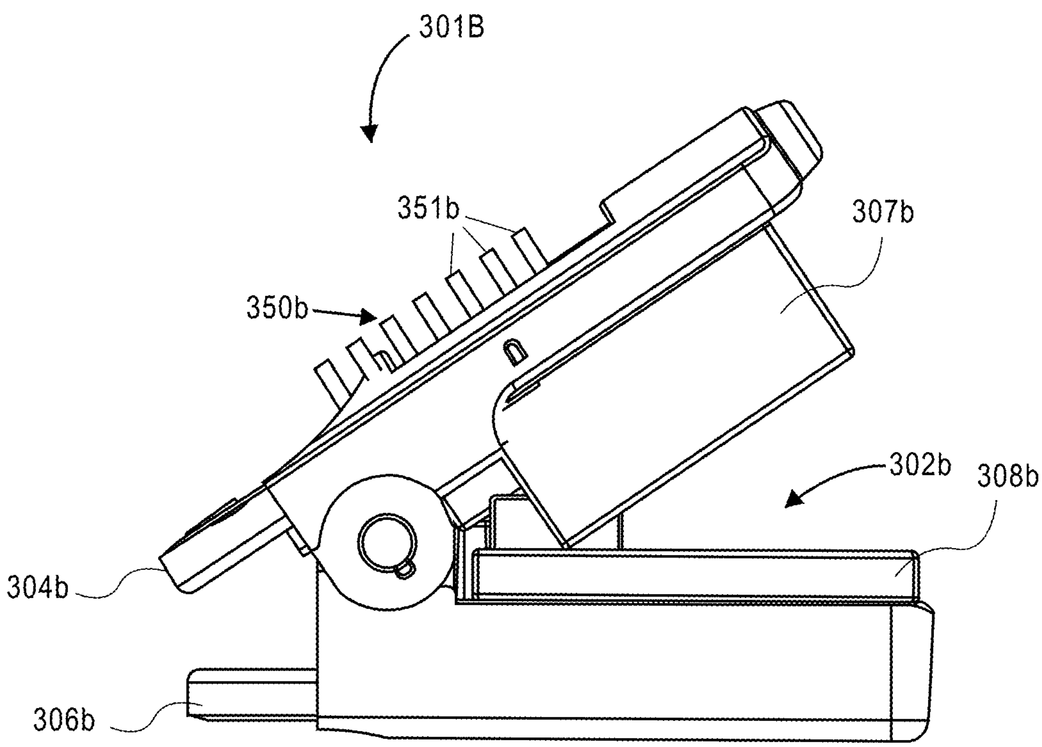


FIG. 3D

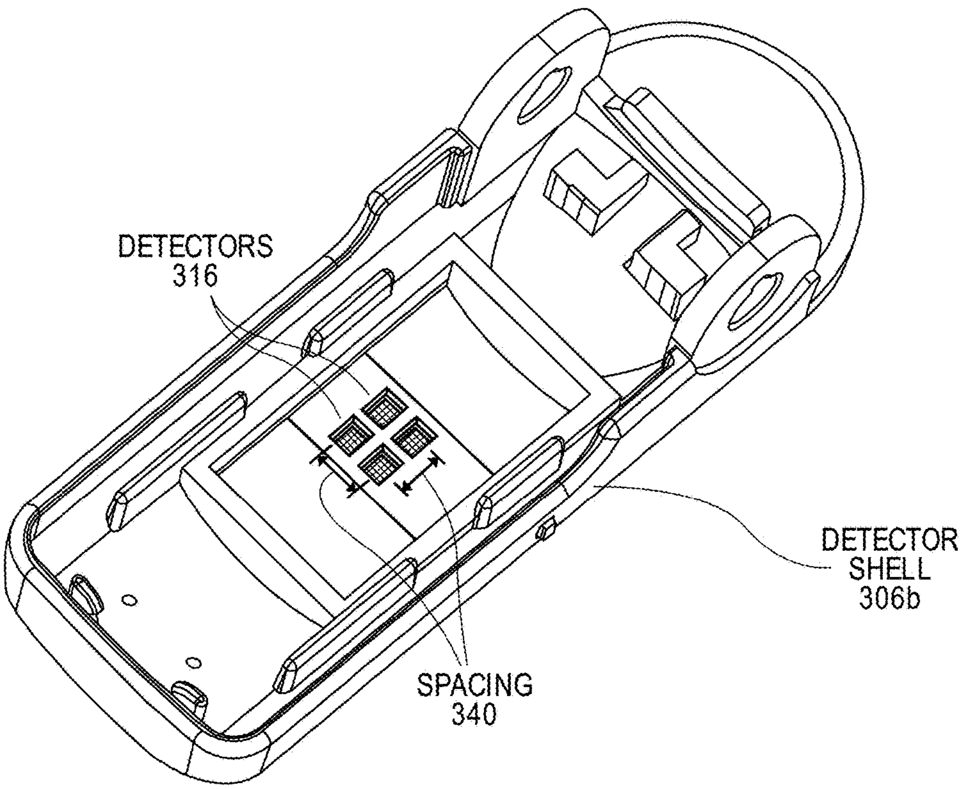


FIG. 3E

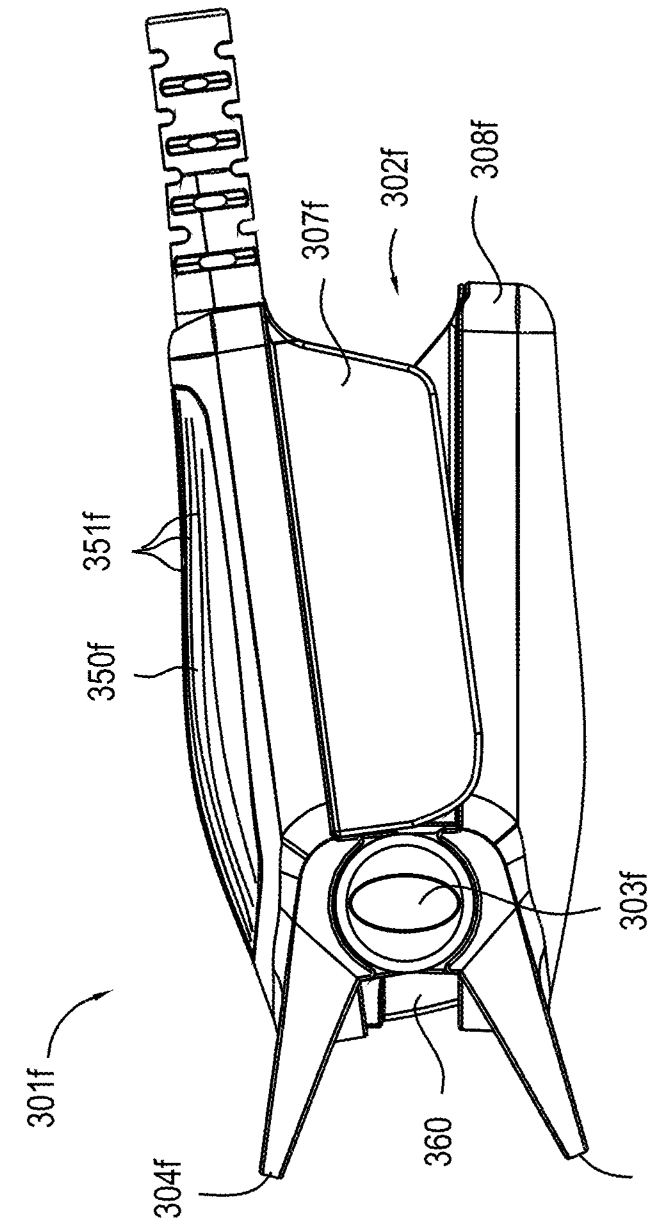


FIG. 3F

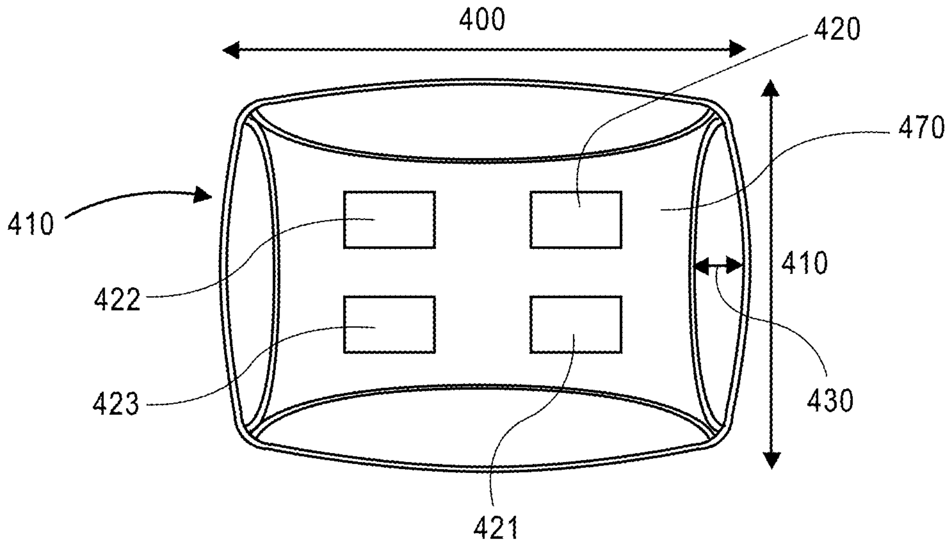


FIG. 4A

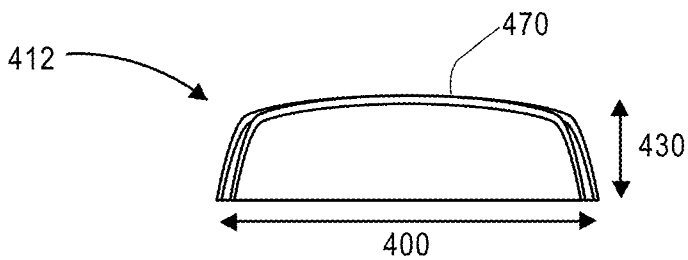


FIG. 4B

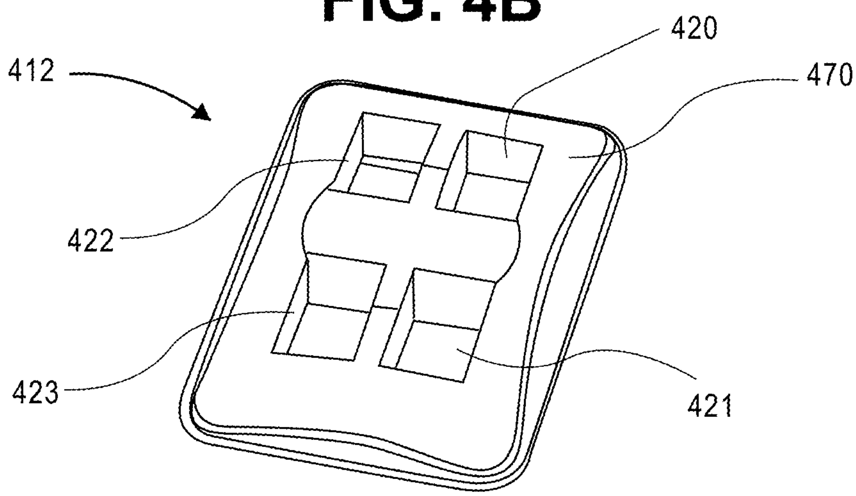


FIG. 4C

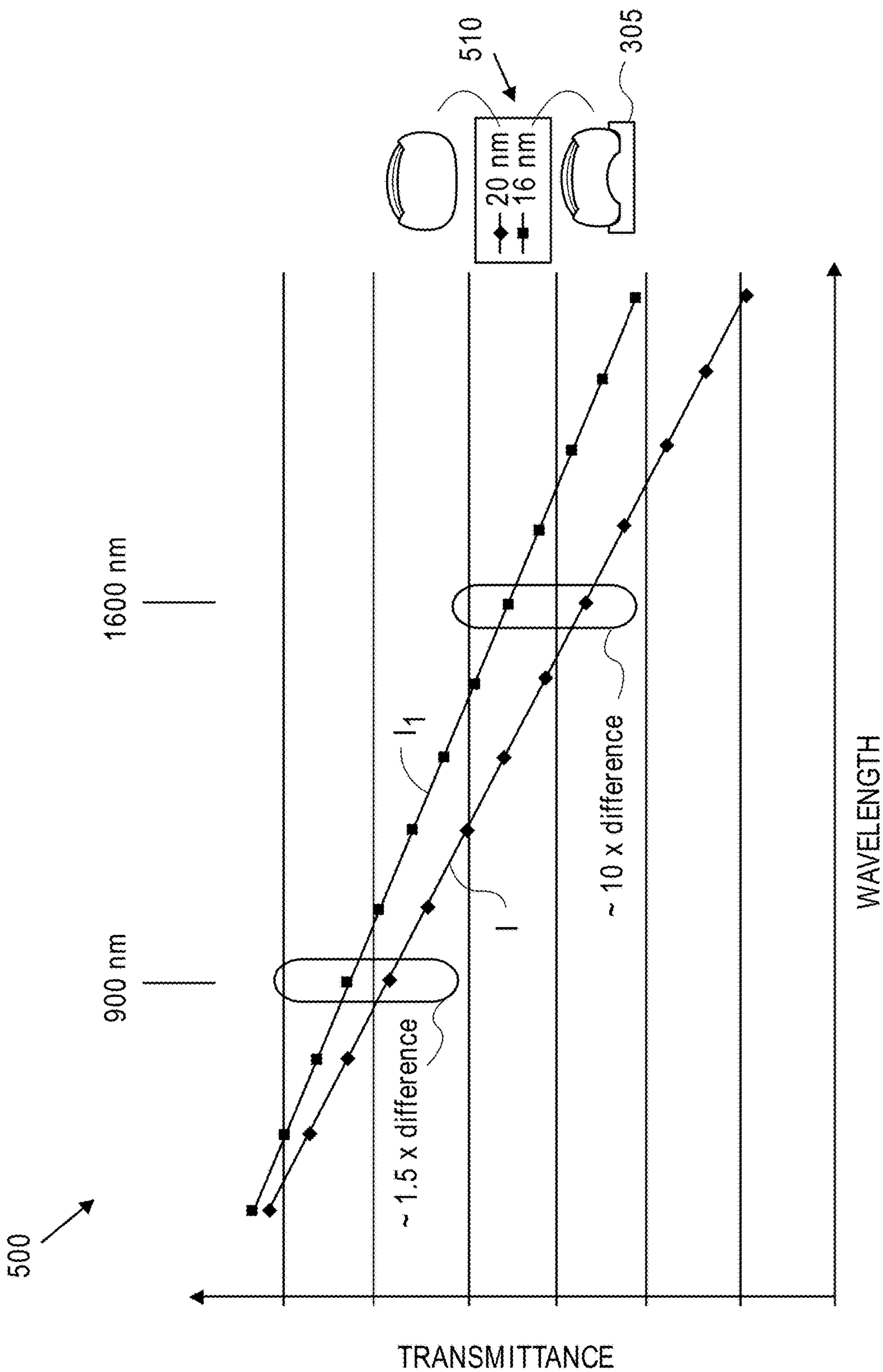

500
510
305
20 nm
16 nm
1600 nm
900 nm
I_1
I
~ 10 x difference
~ 1.5 x difference
WAVELENGTH
TRANSMITTANCE

FIG. 5

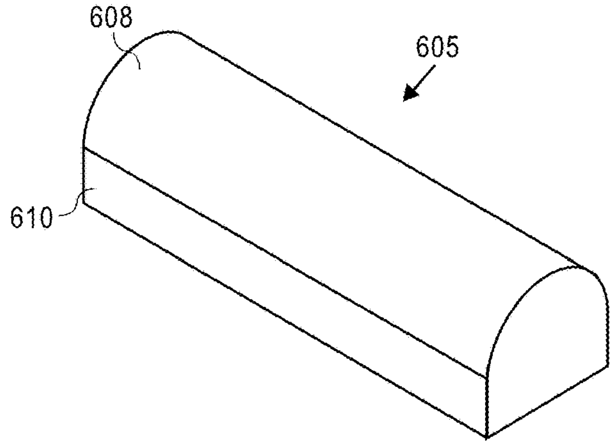


FIG. 6A

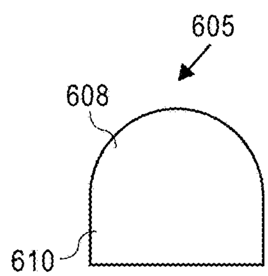


FIG. 6B

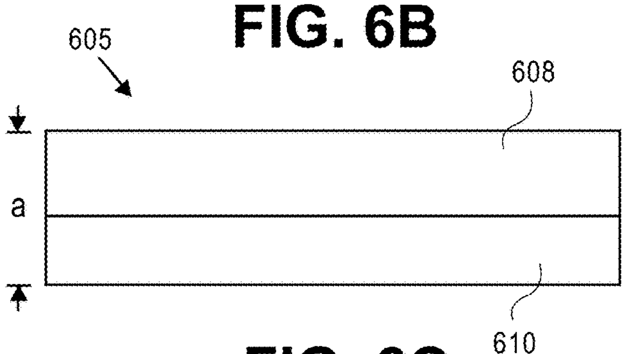


FIG. 6C

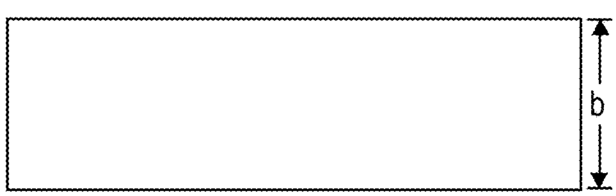


FIG. 6D

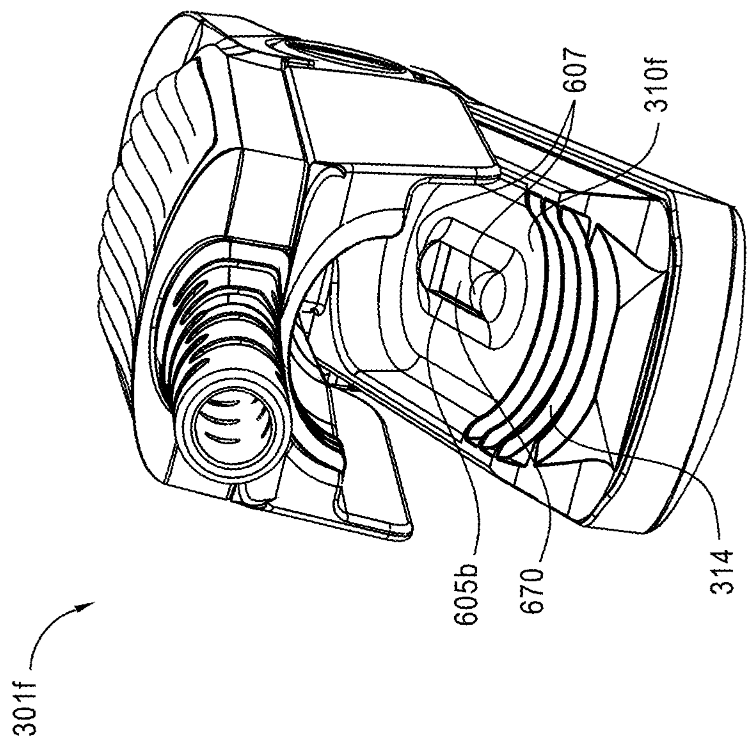


FIG. 6E

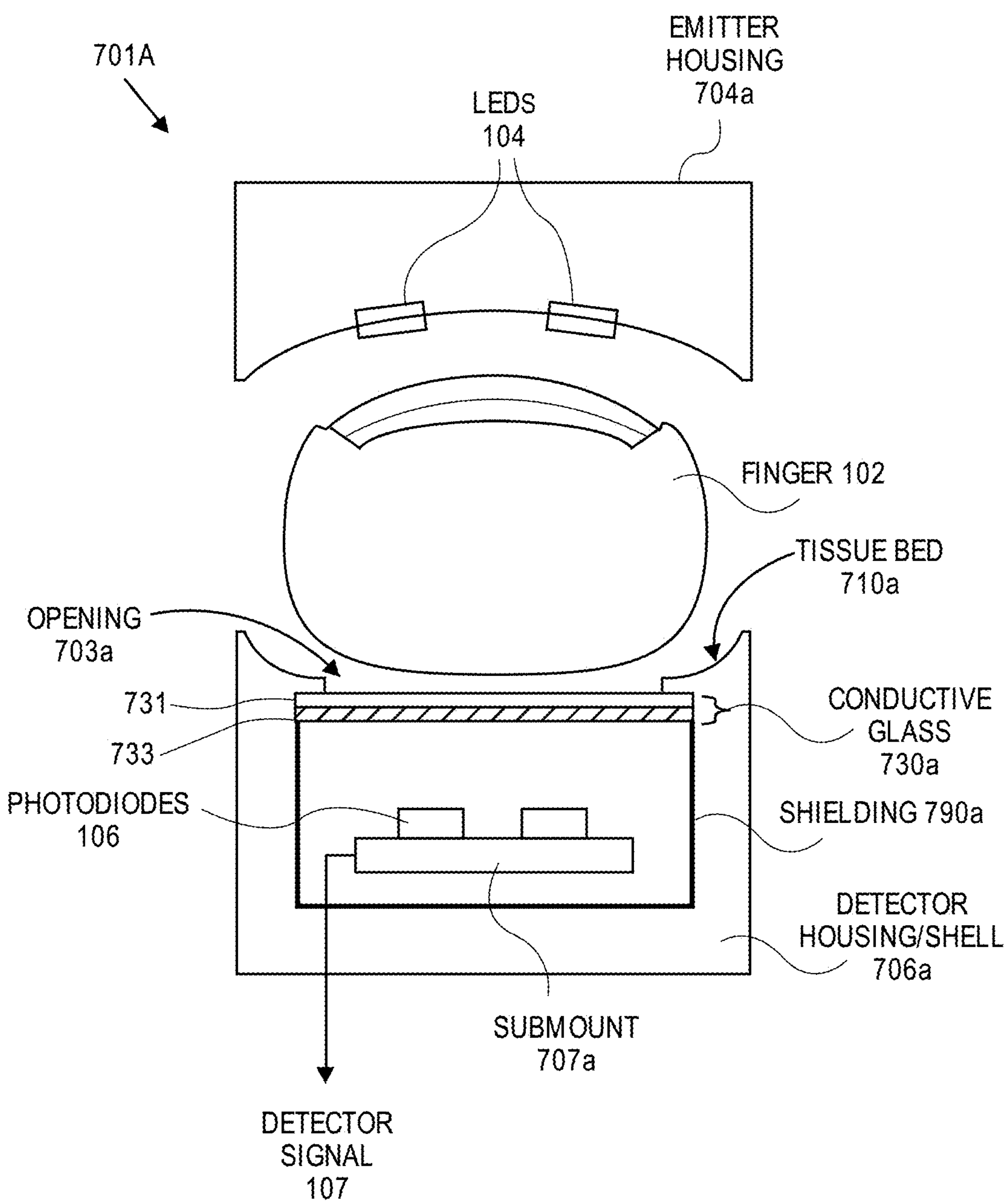

701A
EMITTER
HOUSING
704a
LEDS
104
FINGER 102
TISSUE BED
710a
OPENING
703a
731
733
CONDUCTIVE
GLASS
730a
PHOTODIODES
106
SHIELDING 790a
DETECTOR
HOUSING/SHELL
706a
SUBMOUNT
707a
DETECTOR
SIGNAL
107

FIG. 7A

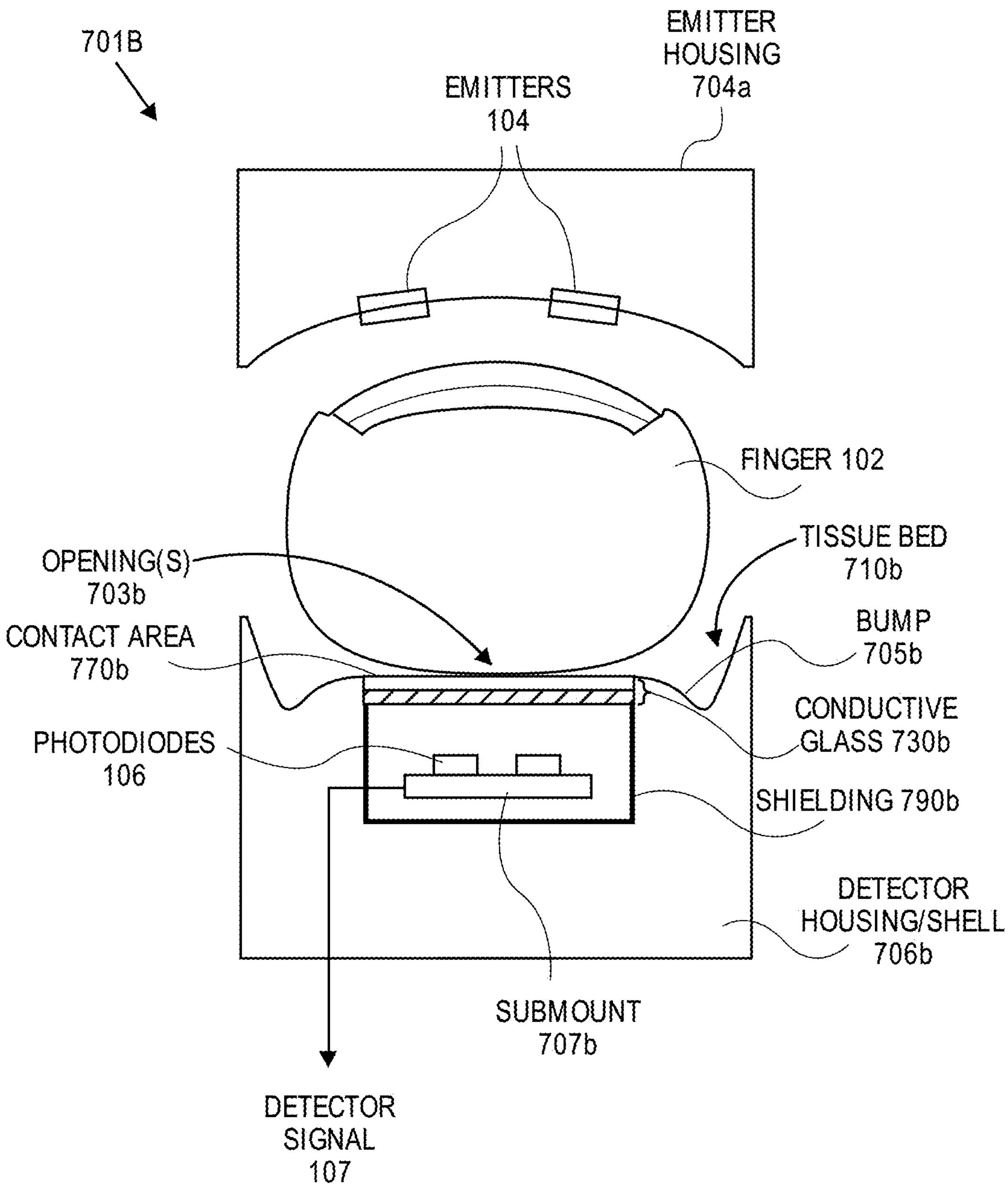

701B
EMITTER HOUSING 704a
EMITTERS 104
FINGER 102
TISSUE BED 710b
OPENING(S) 703b
CONTACT AREA 770b
BUMP 705b
CONDUCTIVE GLASS 730b
PHOTODIODES 106
SHIELDING 790b
DETECTOR HOUSING/SHELL 706b
SUBMOUNT 707b
DETECTOR SIGNAL 107

FIG. 7B

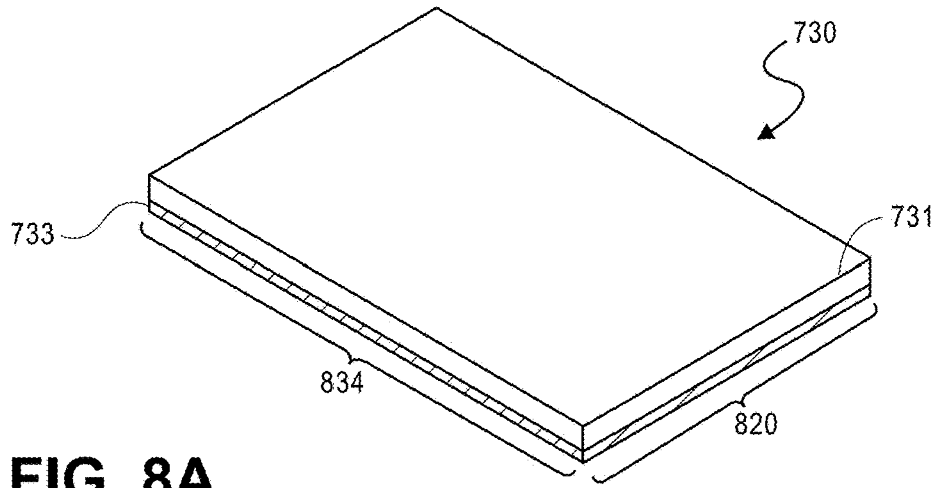


FIG. 8A

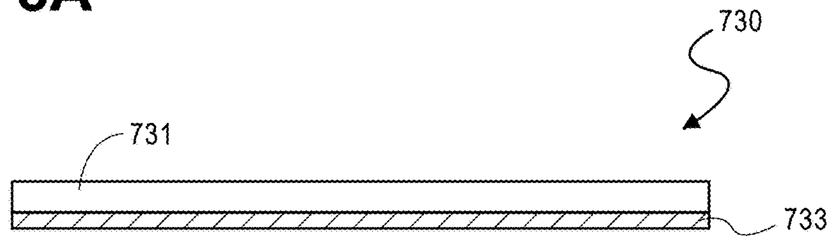


FIG. 8B

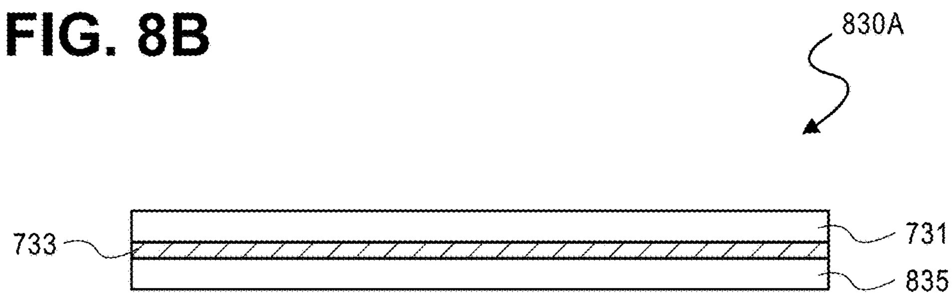


FIG. 8C

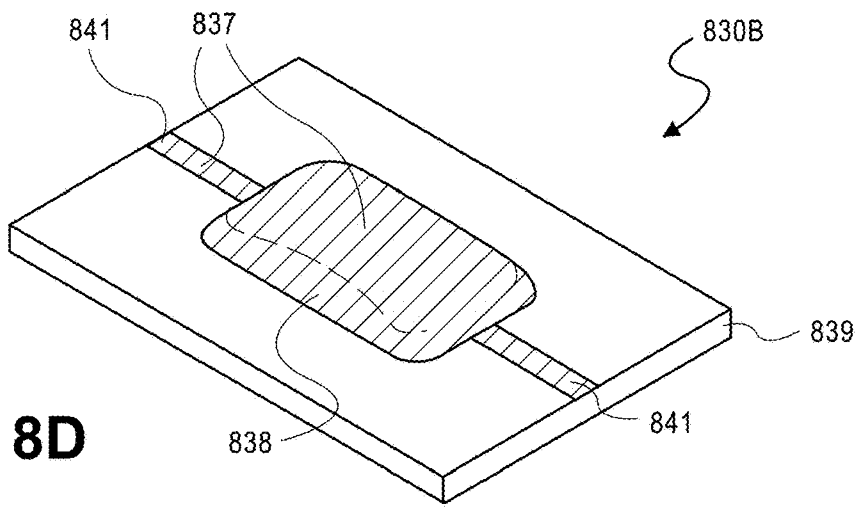


FIG. 8D

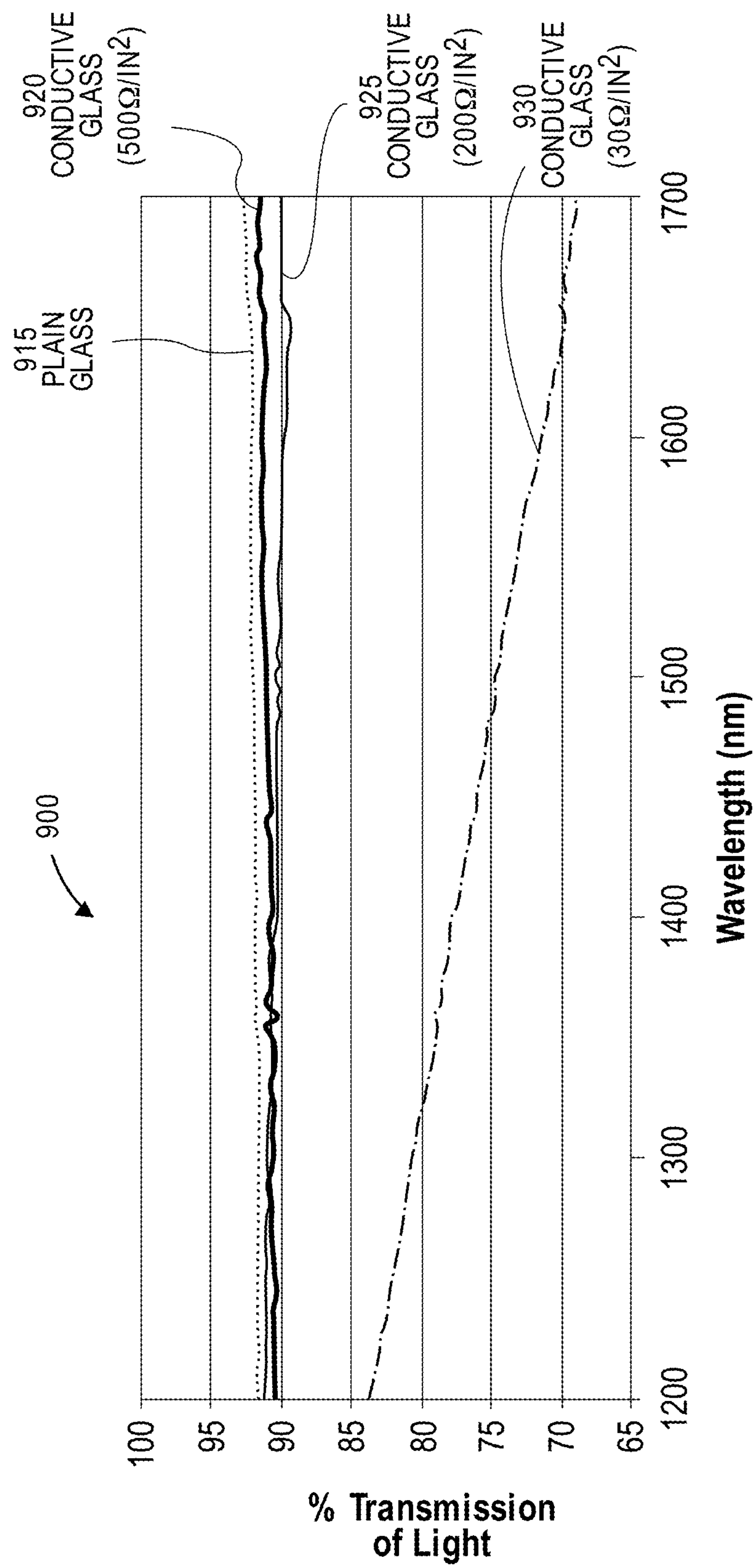

900
915 PLAIN GLASS
920 CONDUCTIVE GLASS (500Ω/IN2)
925 CONDUCTIVE GLASS (200Ω/IN2)
930 CONDUCTIVE GLASS (30Ω/IN2)
100
95
90
85
80
75
70
65
% Transmission of Light
1200
1300
1400
1500
1600
1700
Wavelength (nm)

FIG. 9

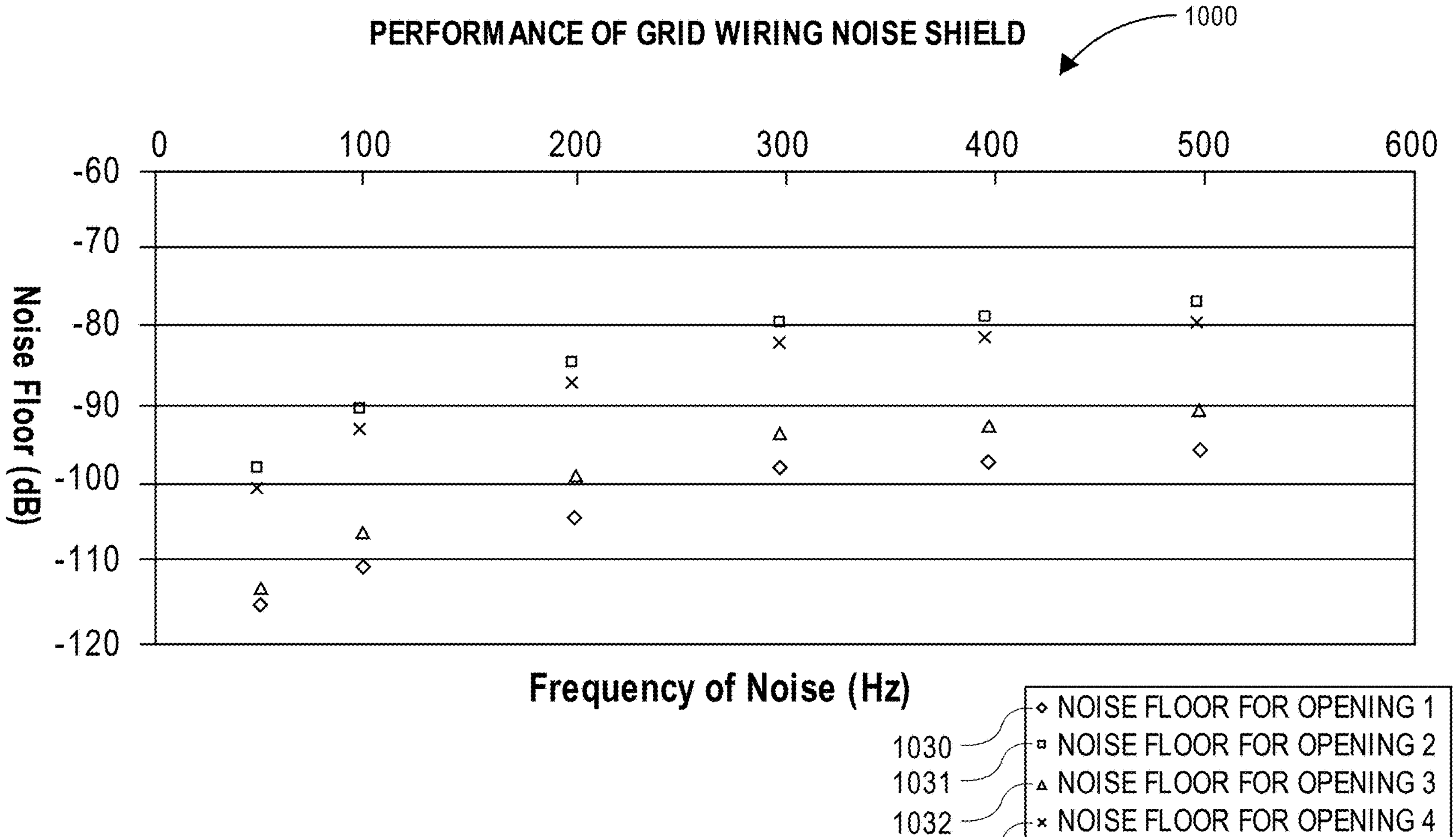

PERFORMANCE OF GRID WIRING NOISE SHIELD
1000
0
100
200
300
400
500
600
-60
-70
-80
-90
-100
-110
-120
Noise Floor (dB)
Frequency of Noise (Hz)
NOISE FLOOR FOR OPENING 1
NOISE FLOOR FOR OPENING 2
NOISE FLOOR FOR OPENING 3
NOISE FLOOR FOR OPENING 4
1030
1031
1032
1033

FIG. 10A

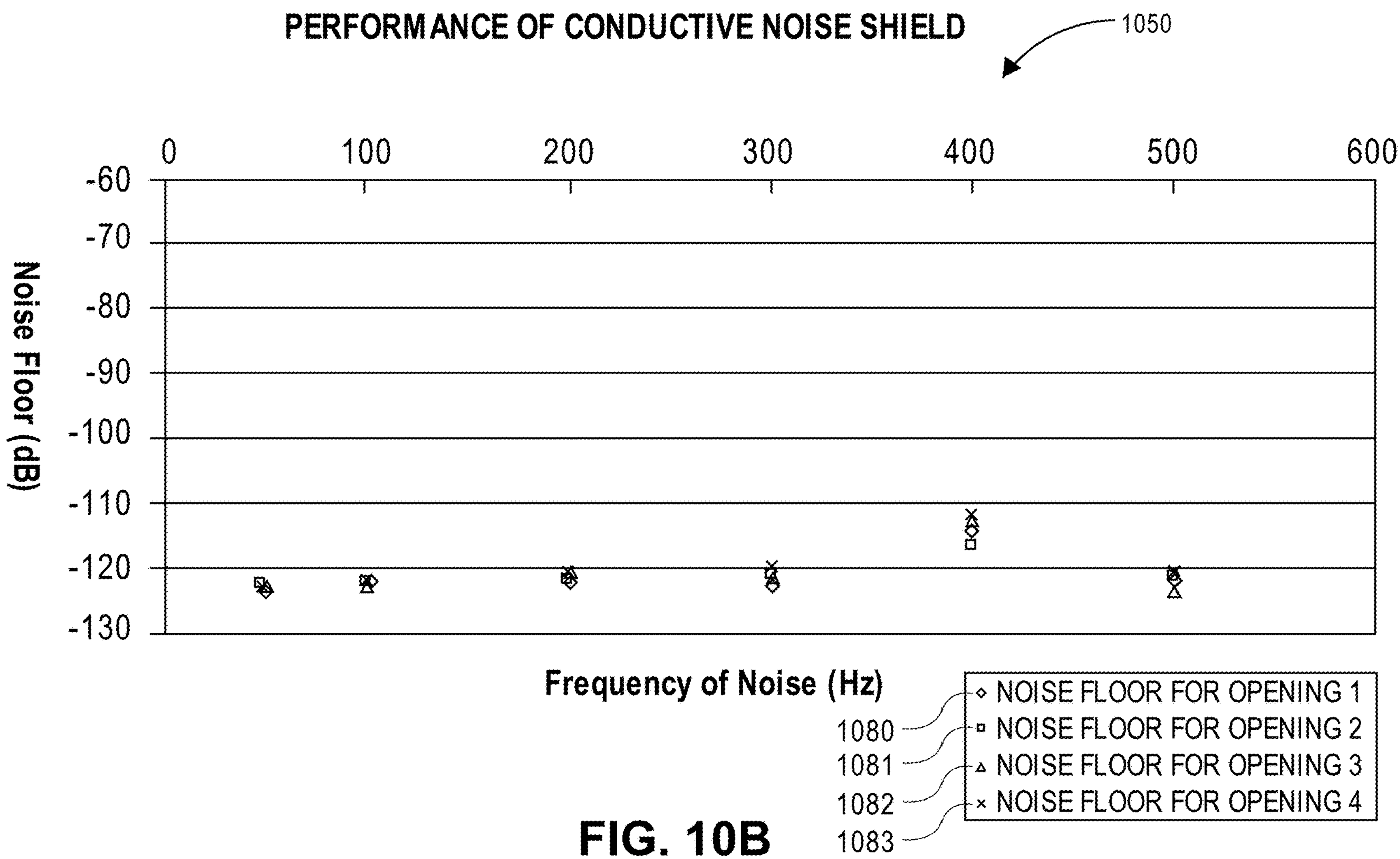

PERFORMANCE OF CONDUCTIVE NOISE SHIELD
1050
0
100
200
300
400
500
600
-60
-70
-80
-90
-100
-110
-120
-130
Noise Floor (dB)
Frequency of Noise (Hz)
NOISE FLOOR FOR OPENING 1
NOISE FLOOR FOR OPENING 2
NOISE FLOOR FOR OPENING 3
NOISE FLOOR FOR OPENING 4
1080
1081
1082
1083

FIG. 10B

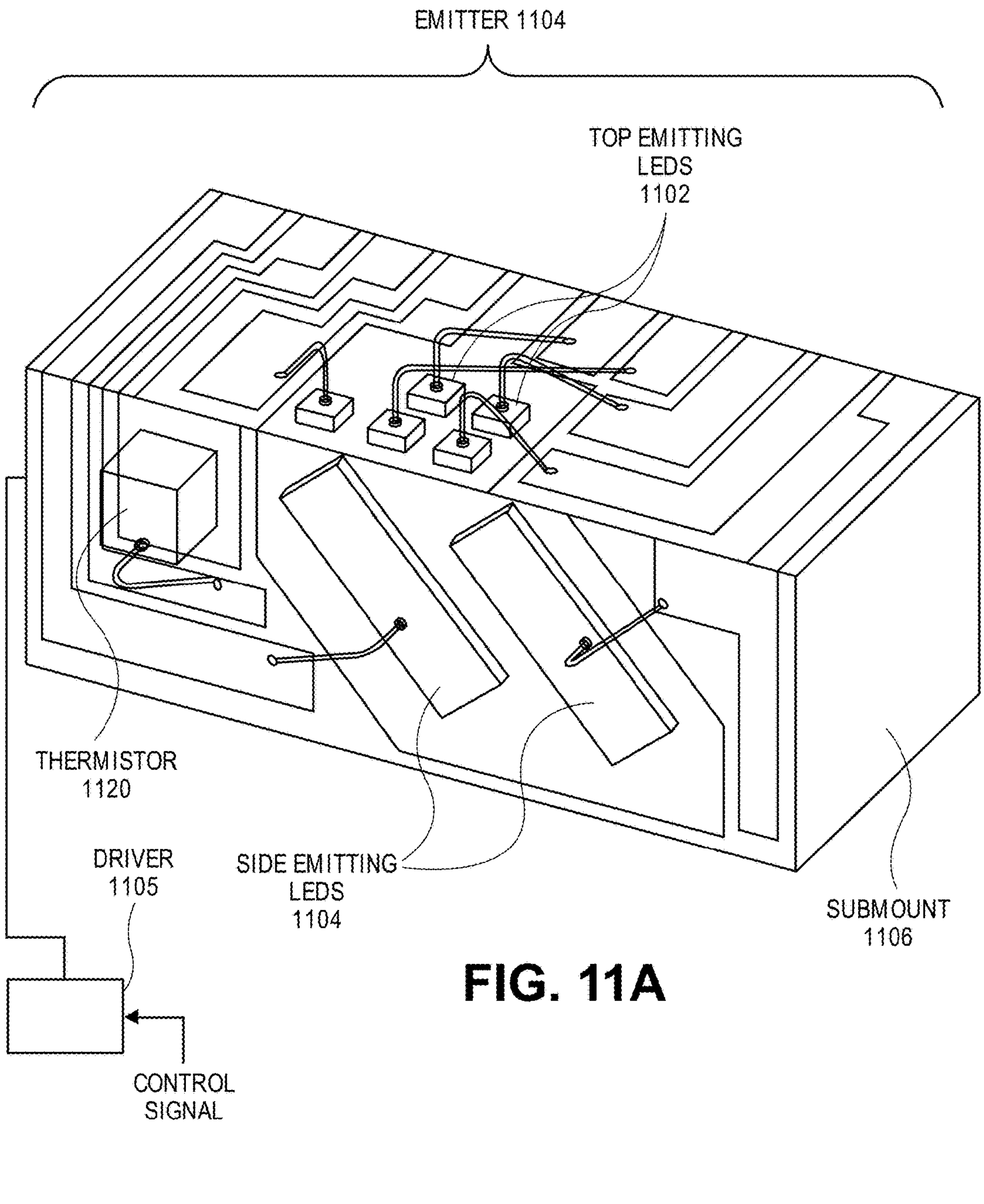
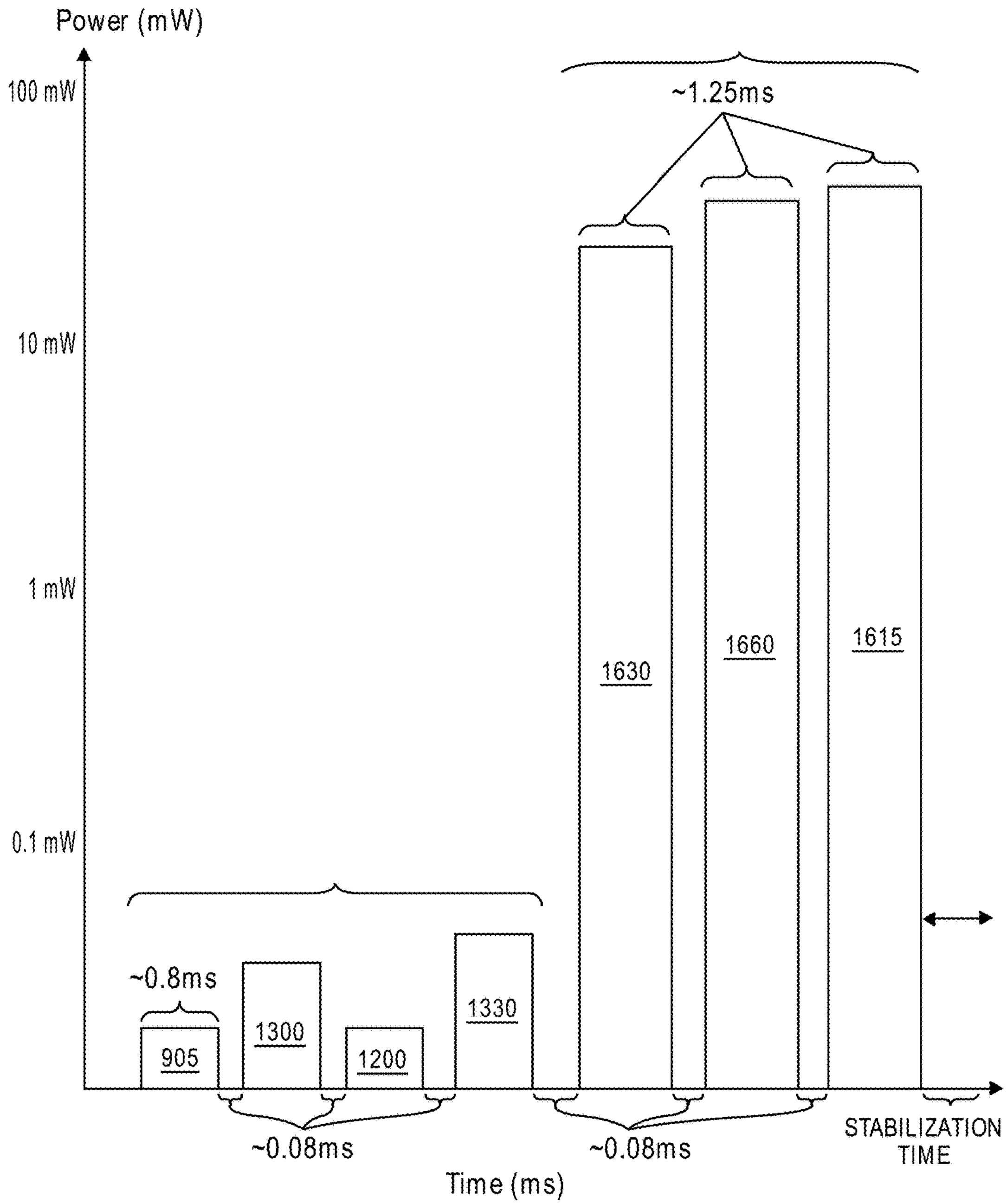

EMITTER 1104
TOP EMITTING LEDS 1102
THERMISTOR 1120
DRIVER 1105
SIDE EMITTING LEDS 1104
SUBMOUNT 1106
CONTROL SIGNAL

FIG. 11A



Power (mW)
100 mW
10 mW
1 mW
0.1 mW
~1.25ms
~0.8ms
905
1300
1200
1330
1630
1660
1615
~0.08ms
~0.08ms
STABILIZATION TIME
Time (ms)

FIG. 11B

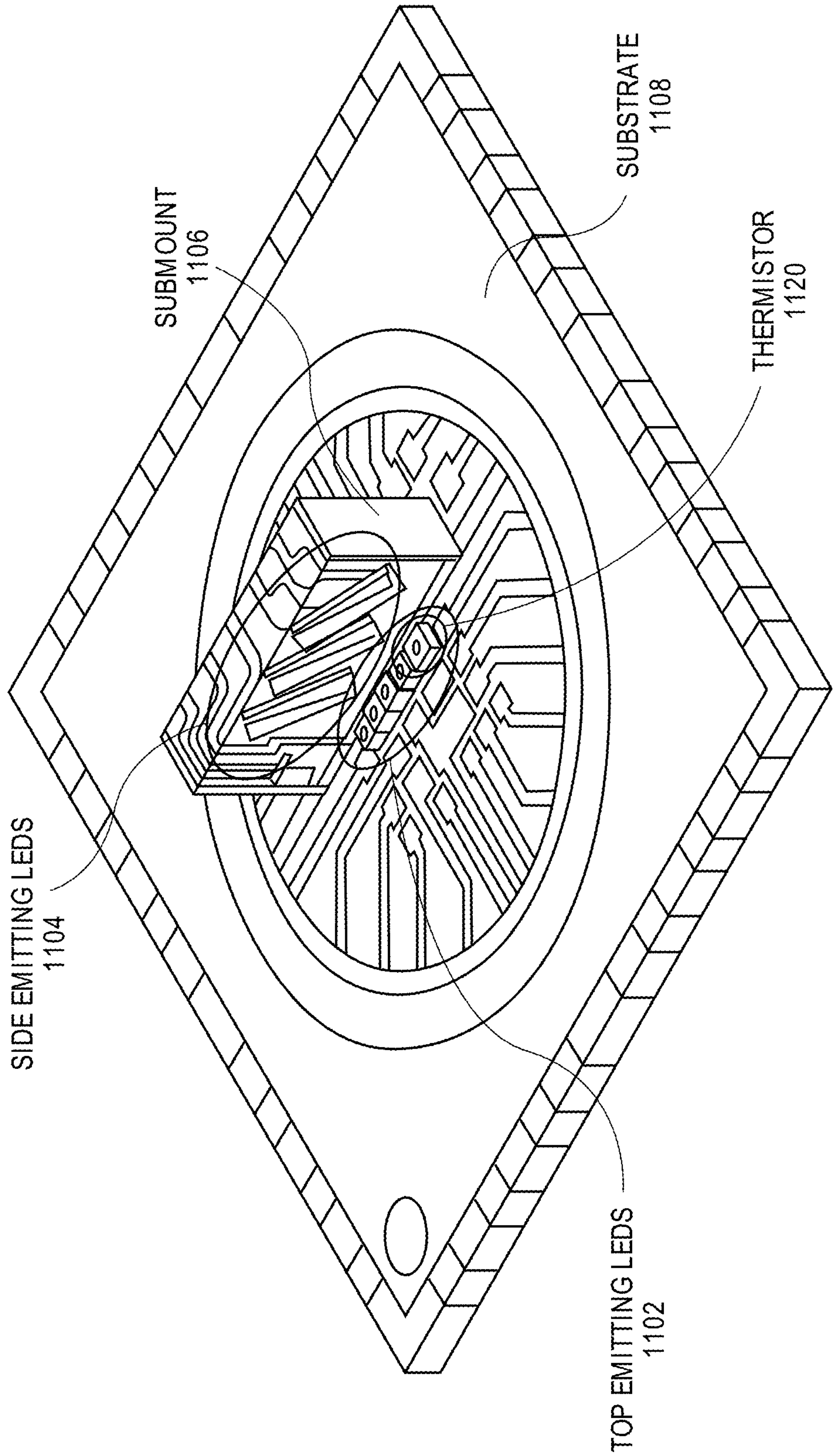

SUBSTRATE
1108
SUBMOUNT
1106
THERMISTOR
1120
SIDE EMITTING LEDS
1104
TOP EMITTING LEDS
1102

FIG. 11C

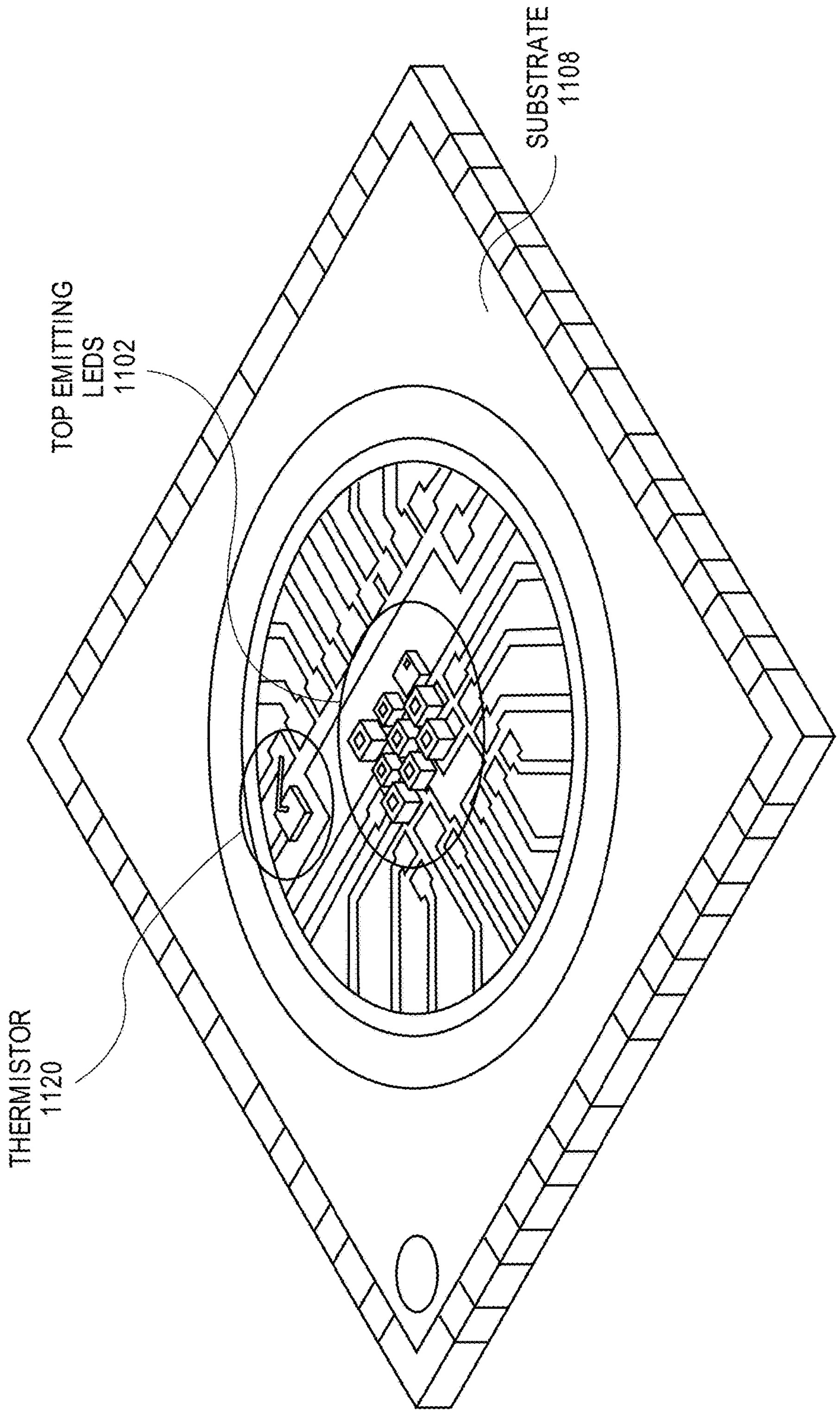


FIG. 11D

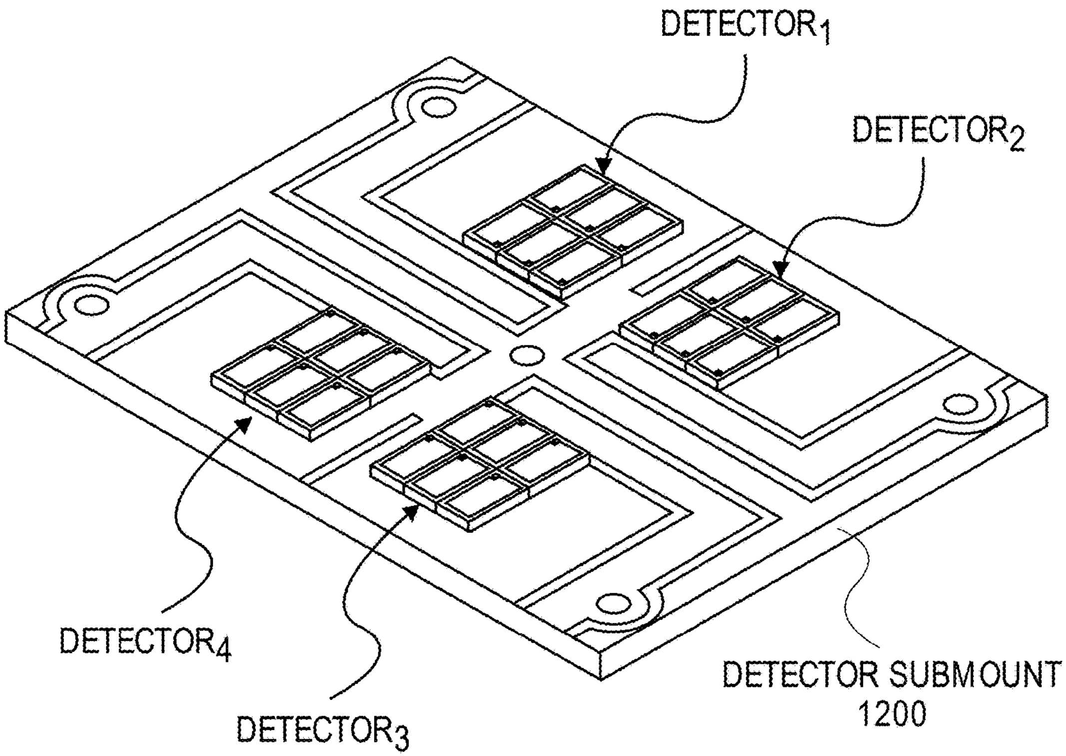

DETECTOR$_1$
DETECTOR$_2$
DETECTOR$_4$
DETECTOR$_3$
DETECTOR SUBMOUNT
1200

FIG. 12A

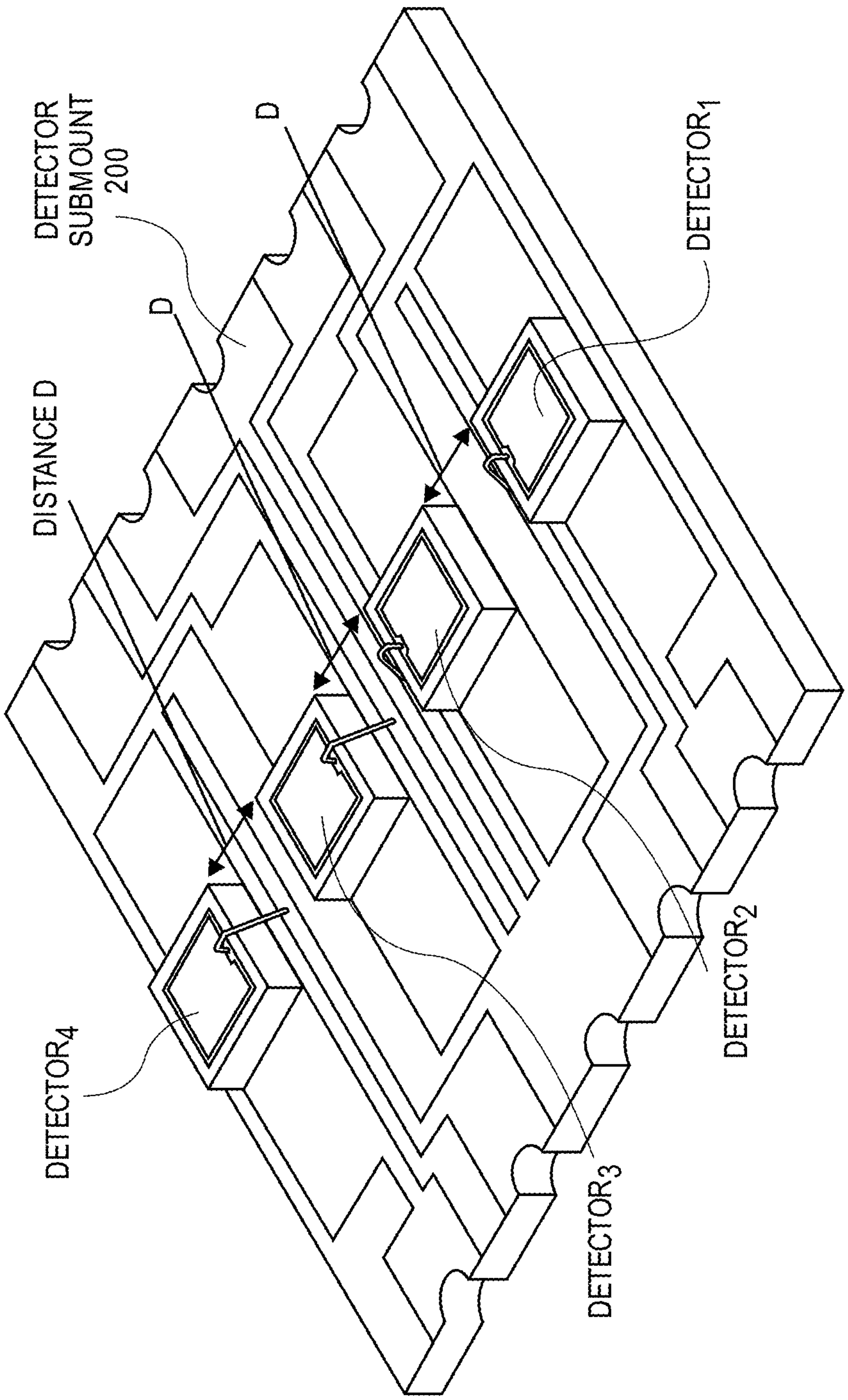

DETECTOR SUBMOUNT 200
D
D
DISTANCE D
DETECTOR$_1$
DETECTOR$_2$
DETECTOR$_3$
DETECTOR$_4$

FIG. 12B

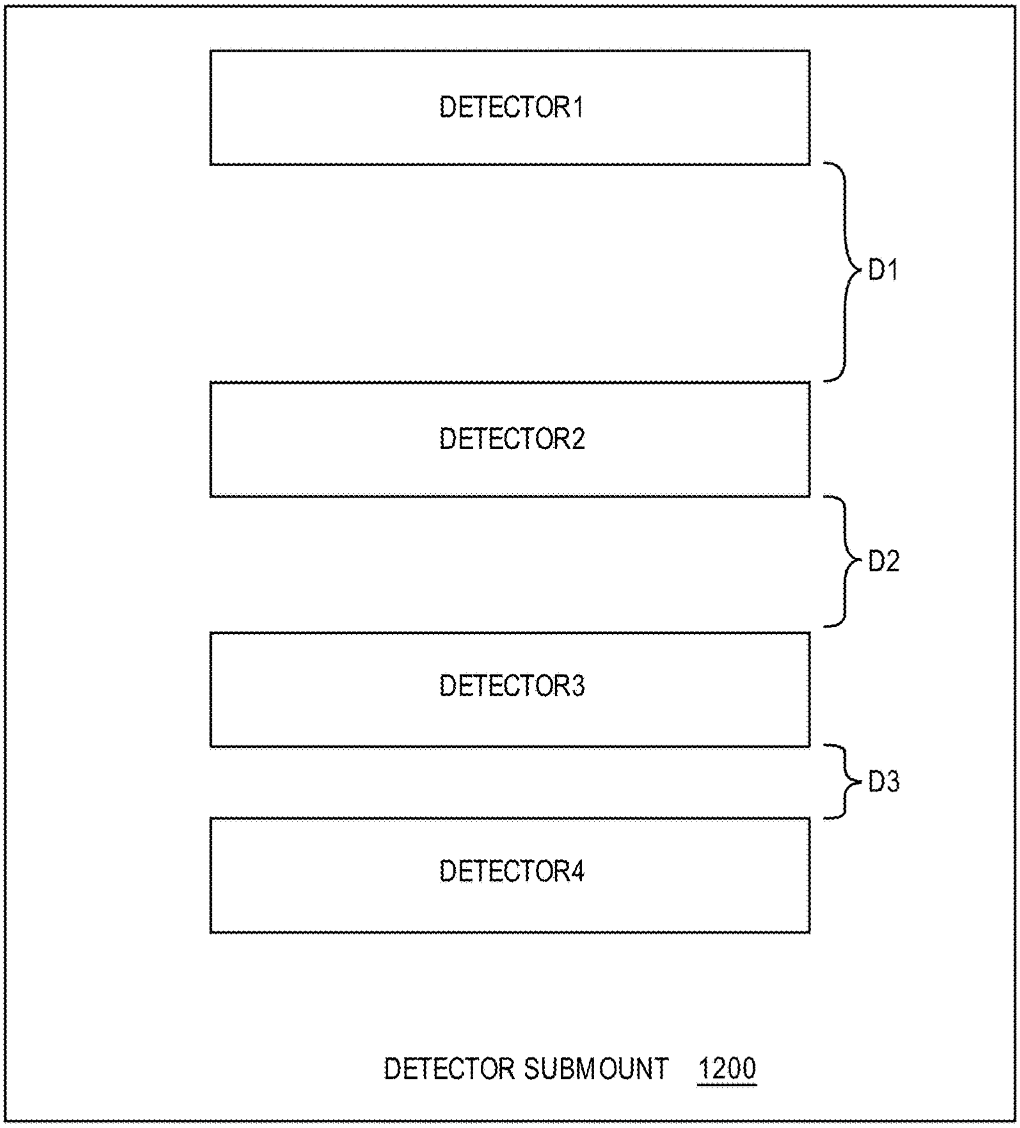

DETECTOR1
D1
DETECTOR2
D2
DETECTOR3
D3
DETECTOR4
DETECTOR SUBMOUNT 1200

FIG. 12C

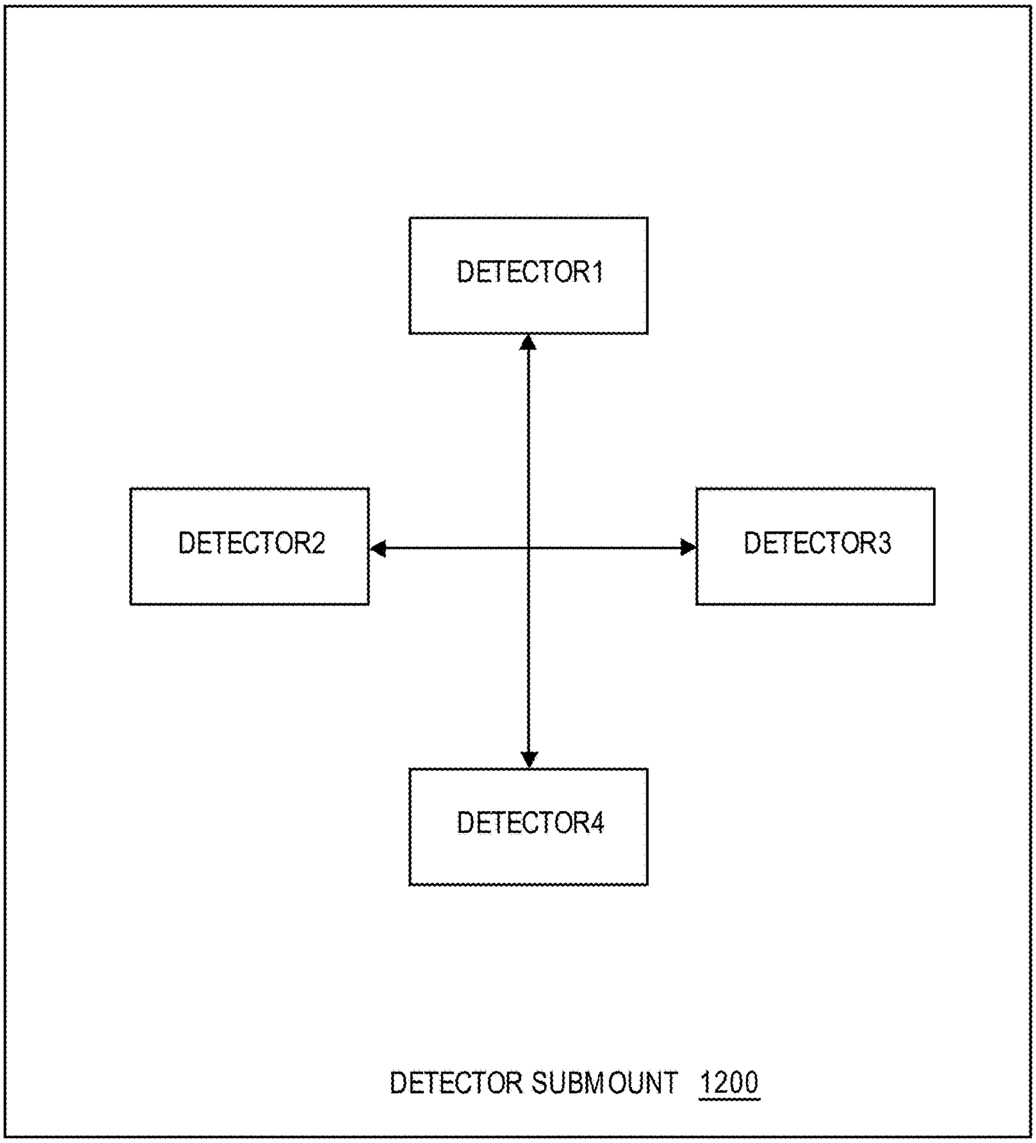

DETECTOR1
DETECTOR2
DETECTOR3
DETECTOR4
DETECTOR SUBMOUNT 1200

FIG. 12D

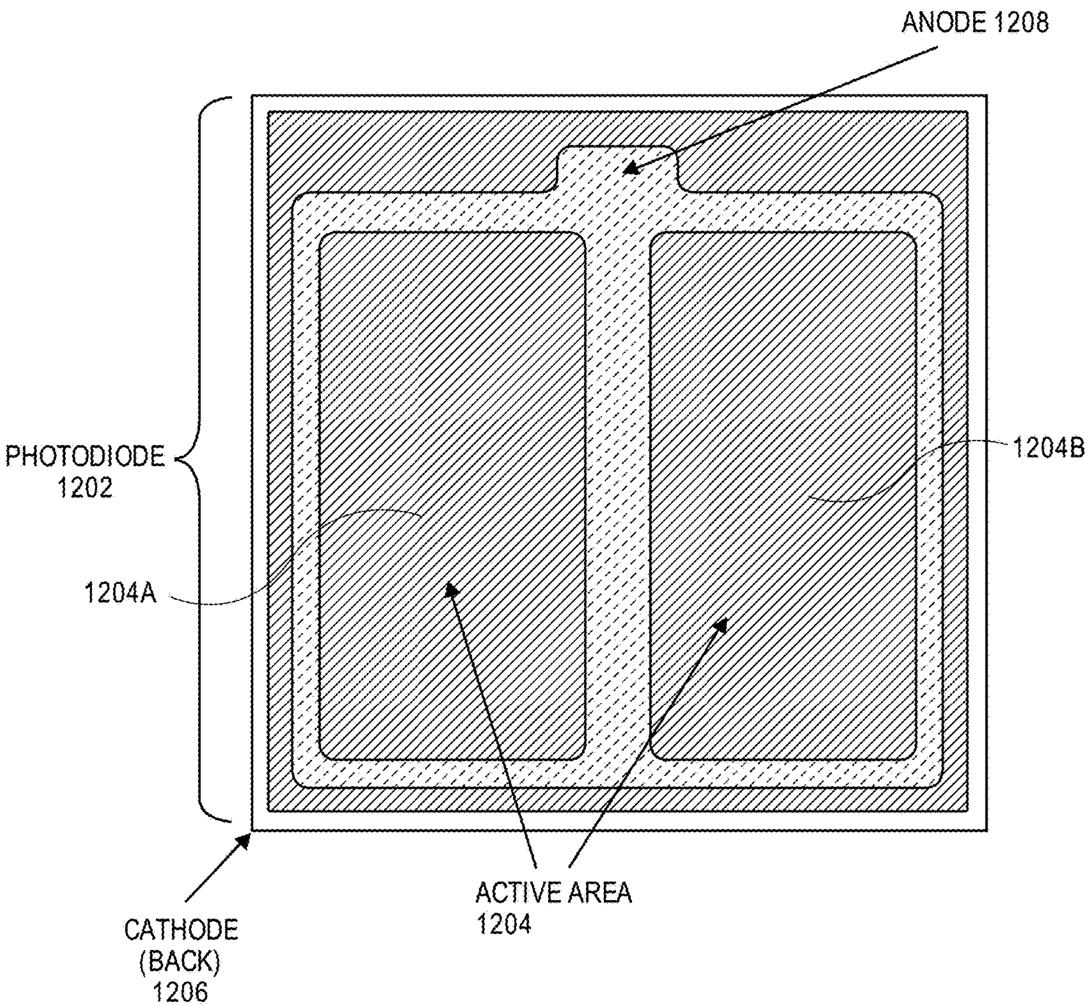

ANODE 1208
PHOTODIODE 1202
1204A
1204B
CATHODE (BACK) 1206
ACTIVE AREA 1204

FIG. 12E

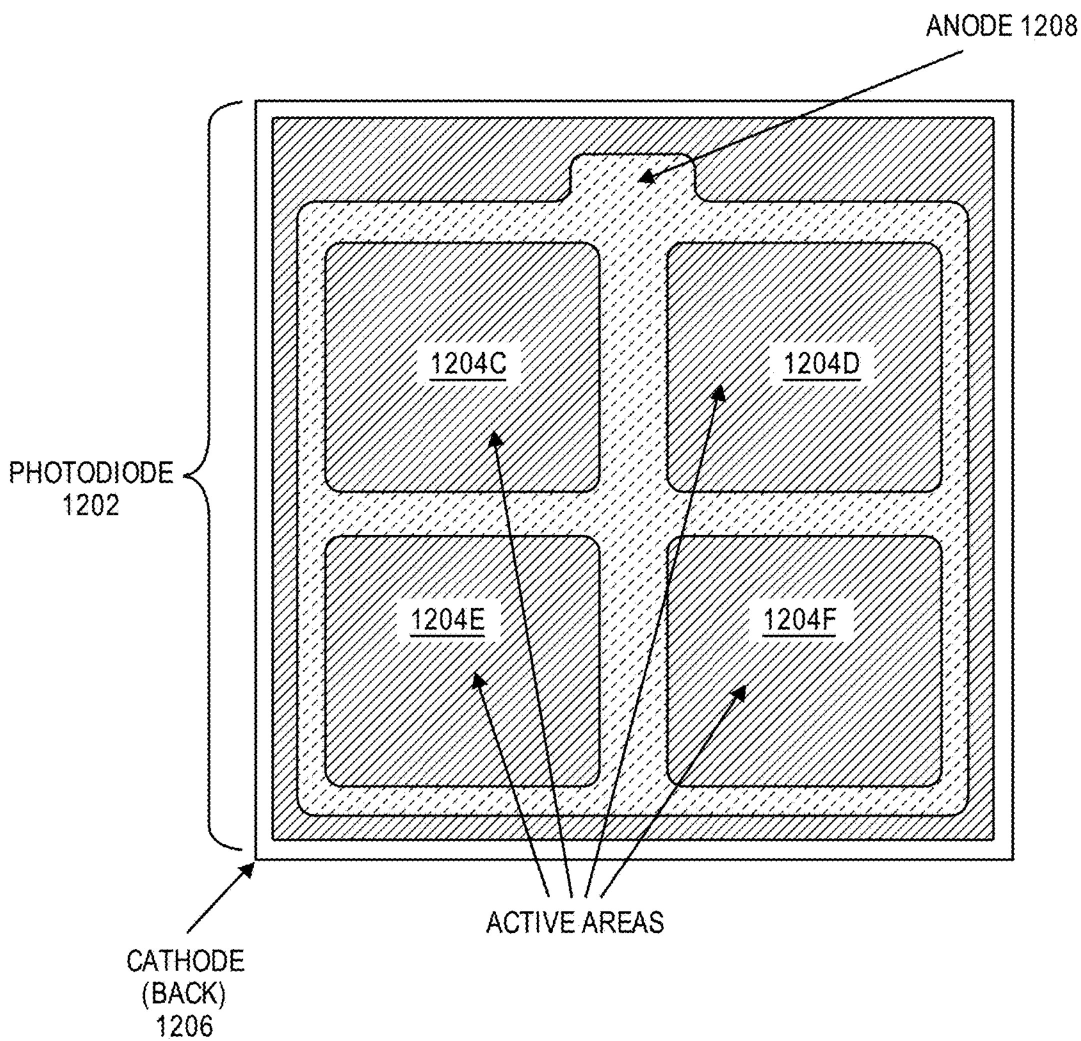

ANODE 1208
1204C
1204D
PHOTODIODE 1202
1204E
1204F
ACTIVE AREAS
CATHODE (BACK) 1206

FIG. 12F

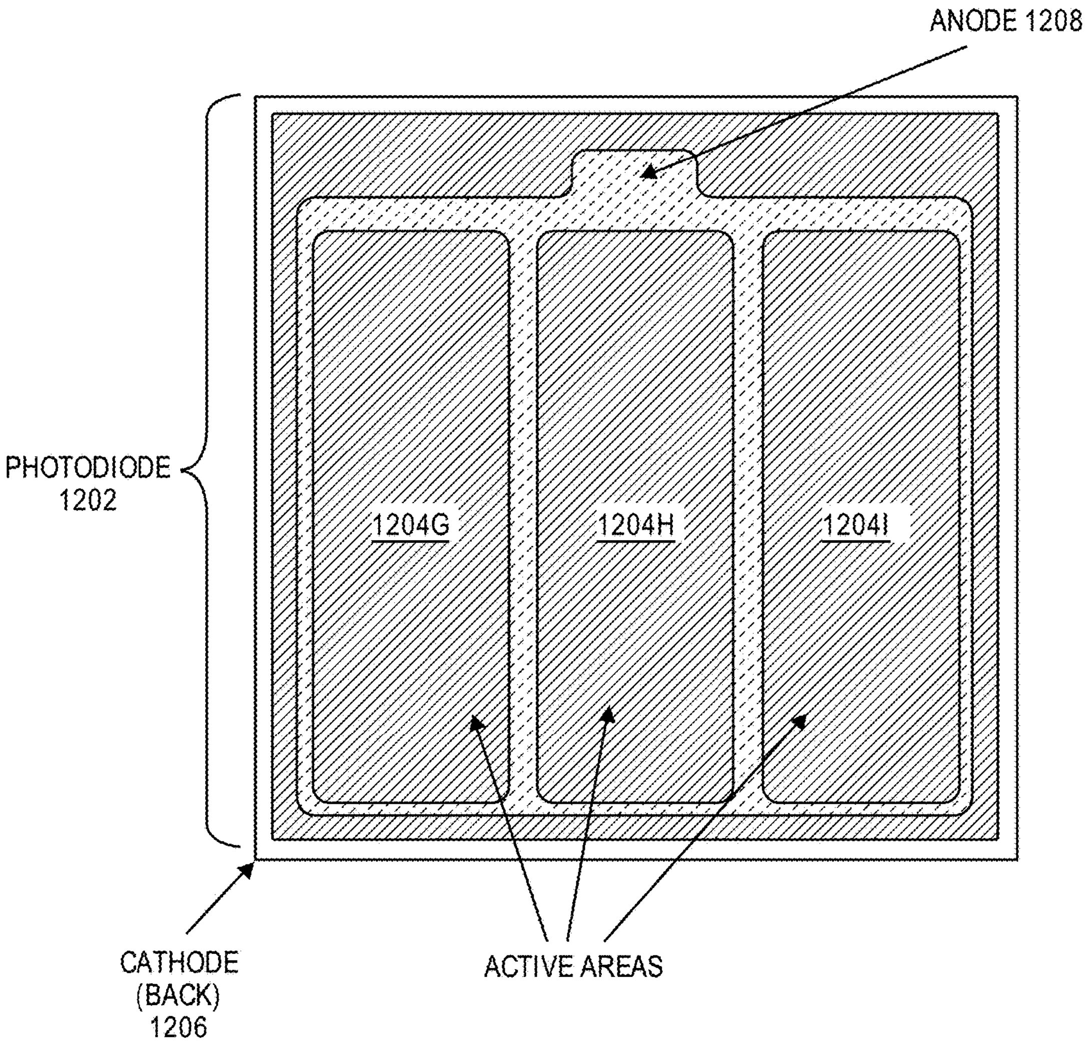

ANODE 1208
PHOTODIODE 1202
1204G
1204H
1204I
CATHODE (BACK) 1206
ACTIVE AREAS

FIG. 12G

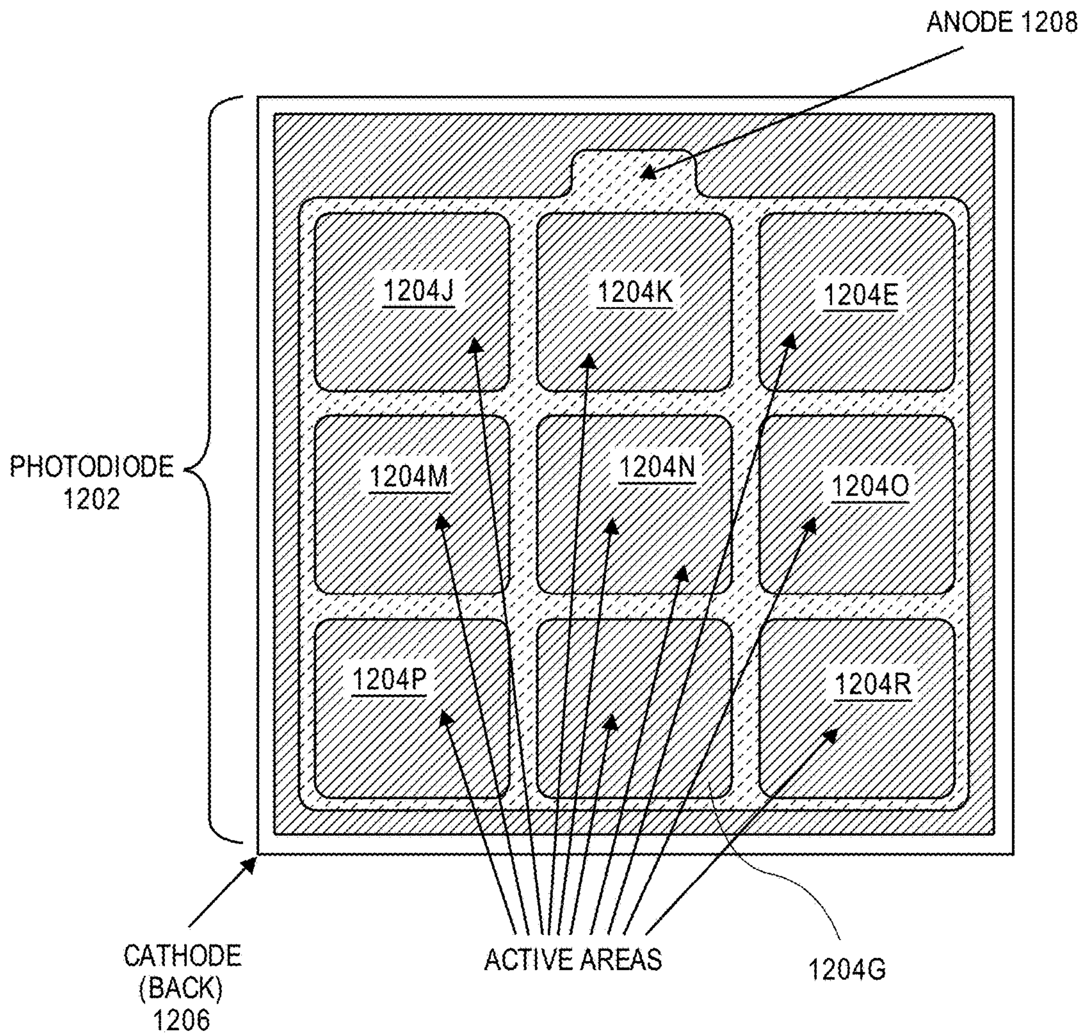

ANODE 1208
1204J
1204K
1204E
PHOTODIODE
1202
1204M
1204N
1204O
1204P
1204R
CATHODE
(BACK)
1206
ACTIVE AREAS
1204G

FIG. 12H

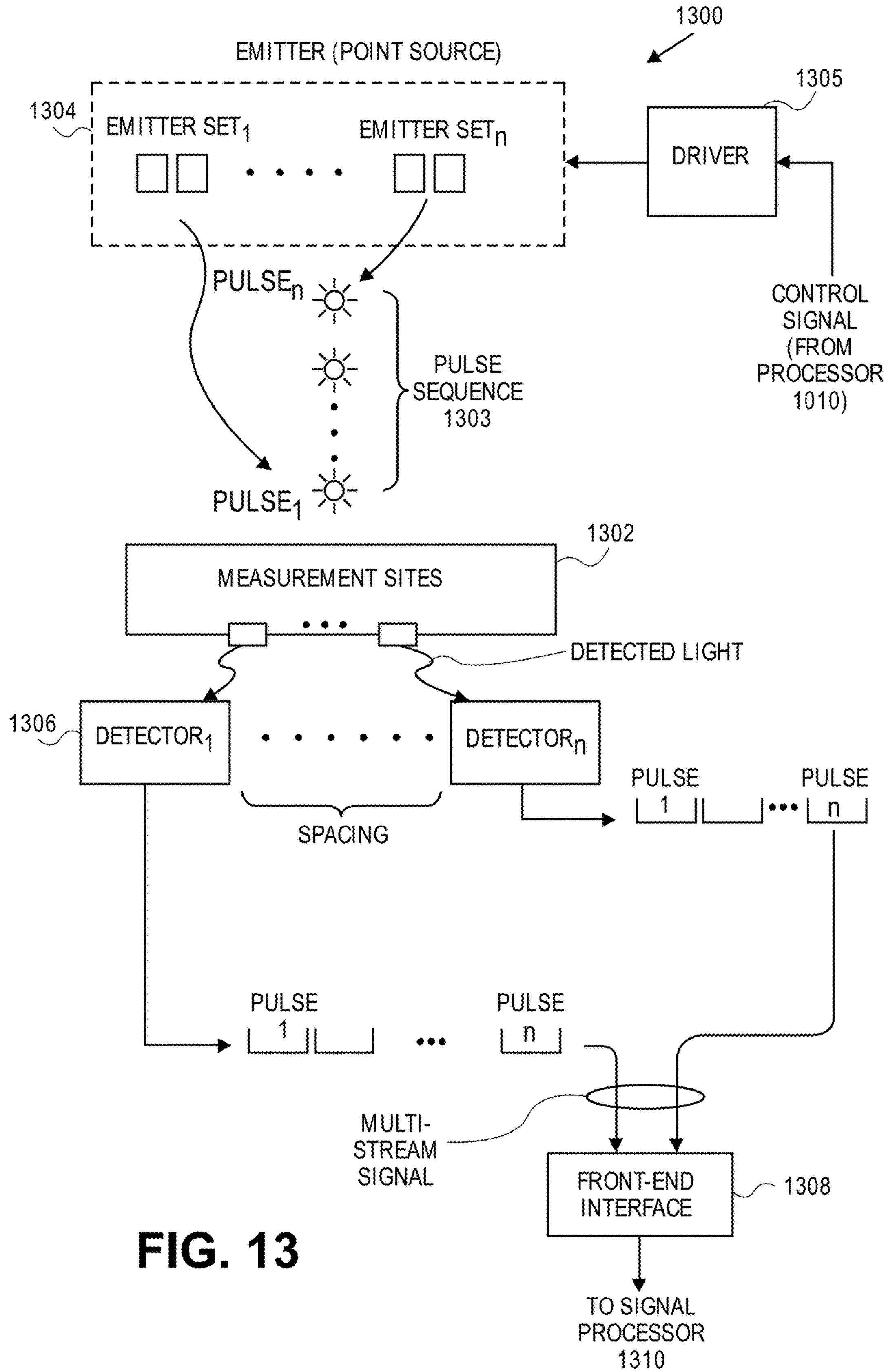

1300
EMITTER (POINT SOURCE)
1305
1304
EMITTER SET$_1$
EMITTER SET$_n$
DRIVER
PULSE$_n$
CONTROL SIGNAL (FROM PROCESSOR 1010)
PULSE SEQUENCE 1303
PULSE$_1$
1302
MEASUREMENT SITES
DETECTED LIGHT
1306
DETECTOR$_1$
DETECTOR$_n$
PULSE 1
PULSE n
SPACING
PULSE 1
PULSE n
MULTI-STREAM SIGNAL
FRONT-END INTERFACE
1308
TO SIGNAL PROCESSOR 1310

FIG. 13

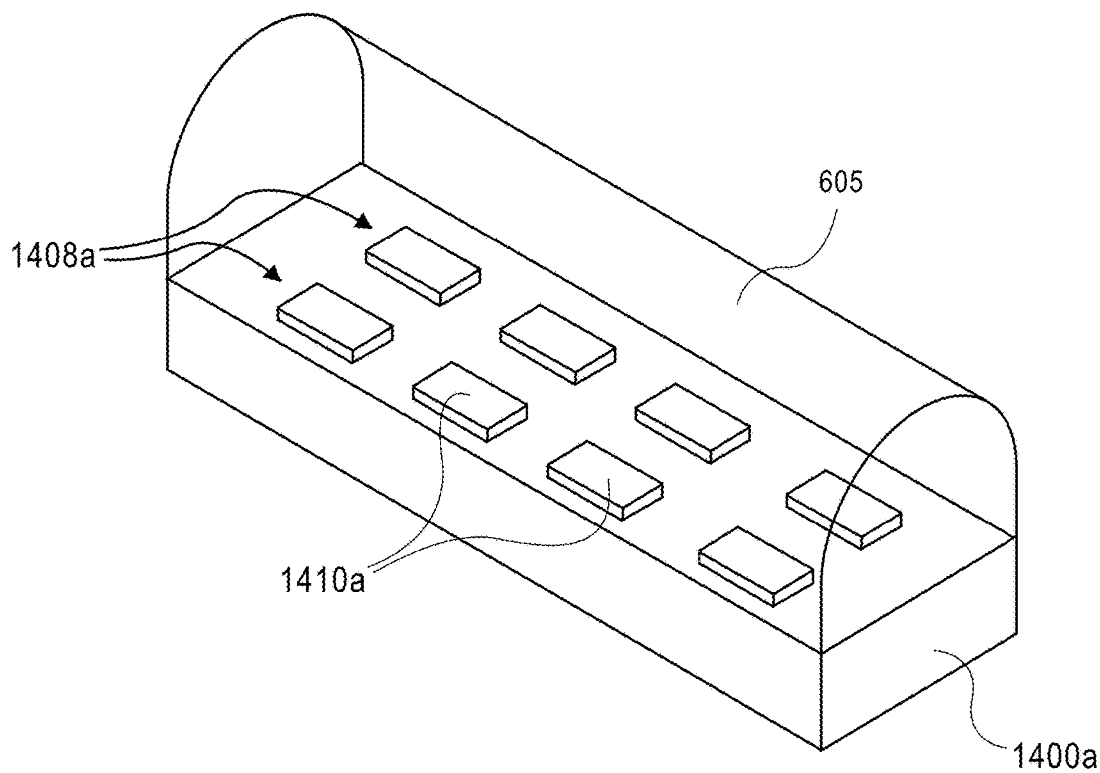


FIG. 14A

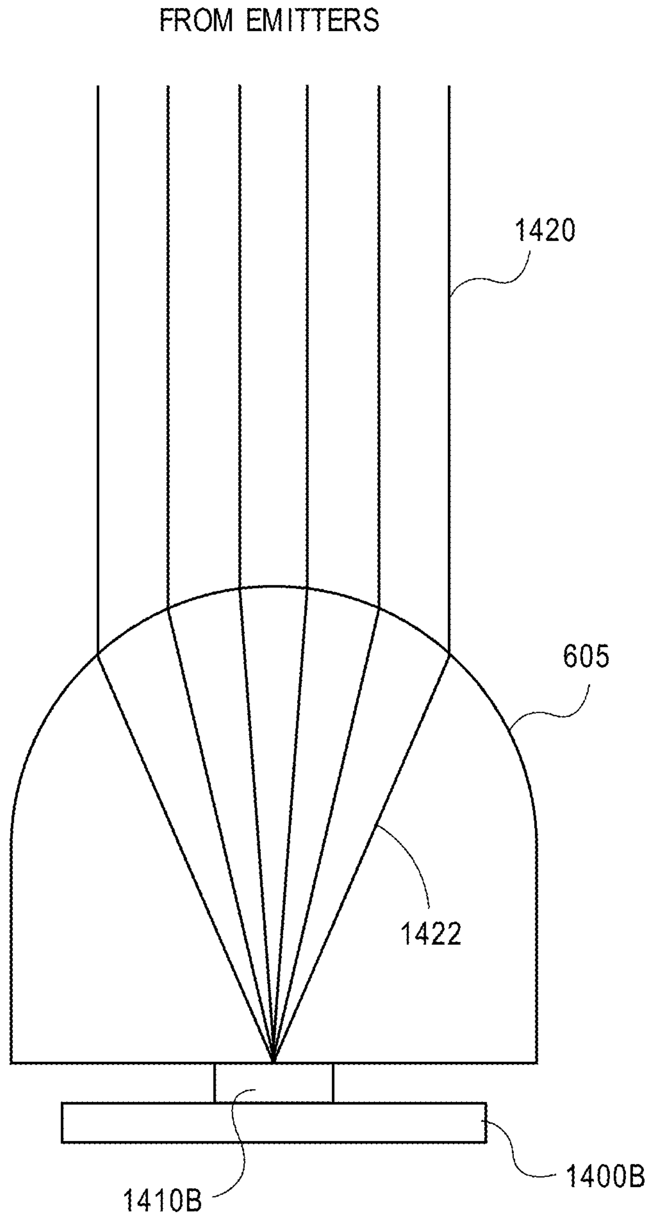


FIG. 14B

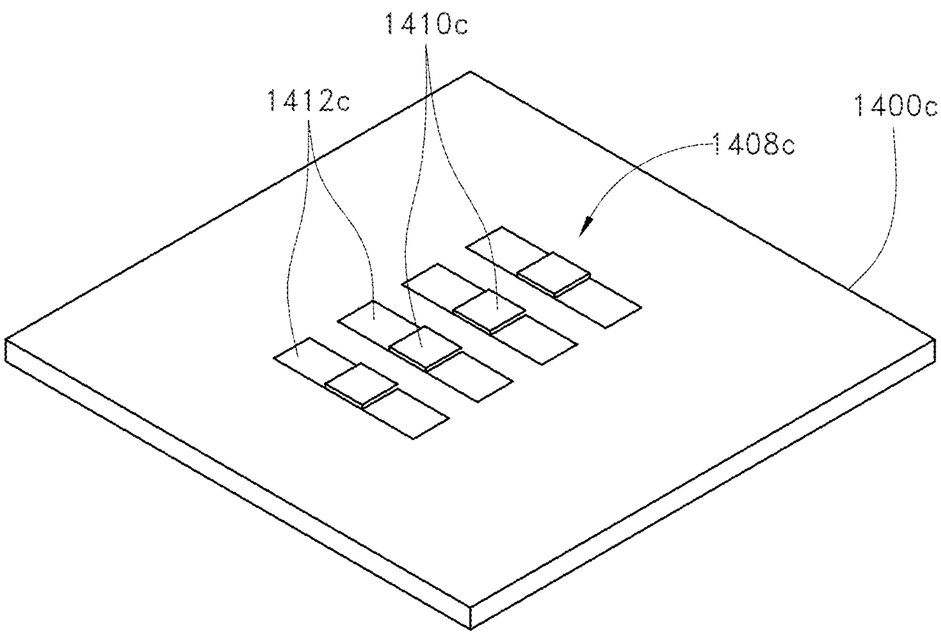


FIG. 14C

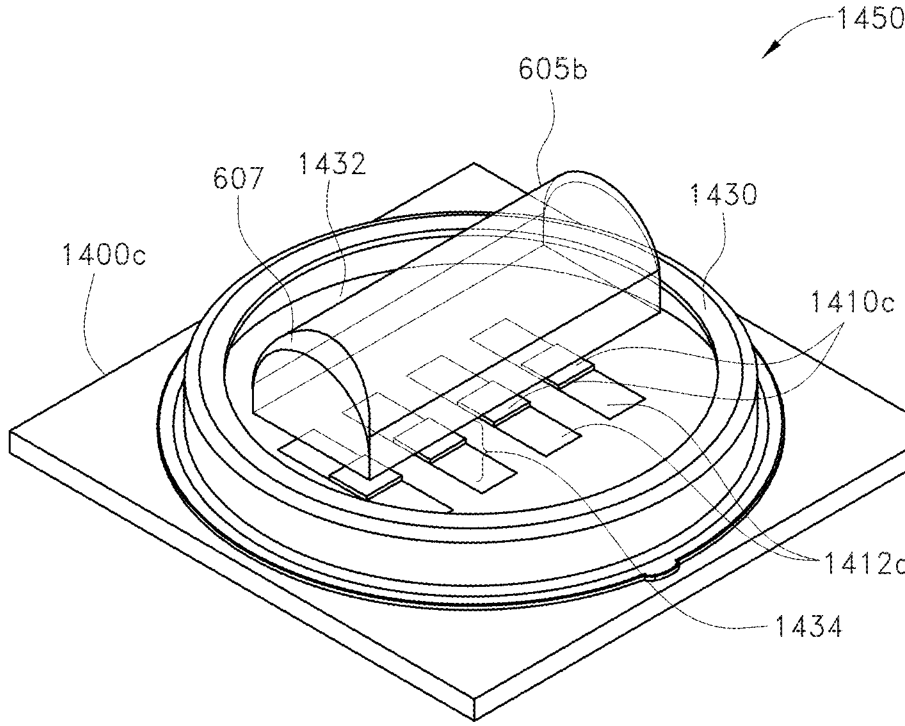


FIG. 14D

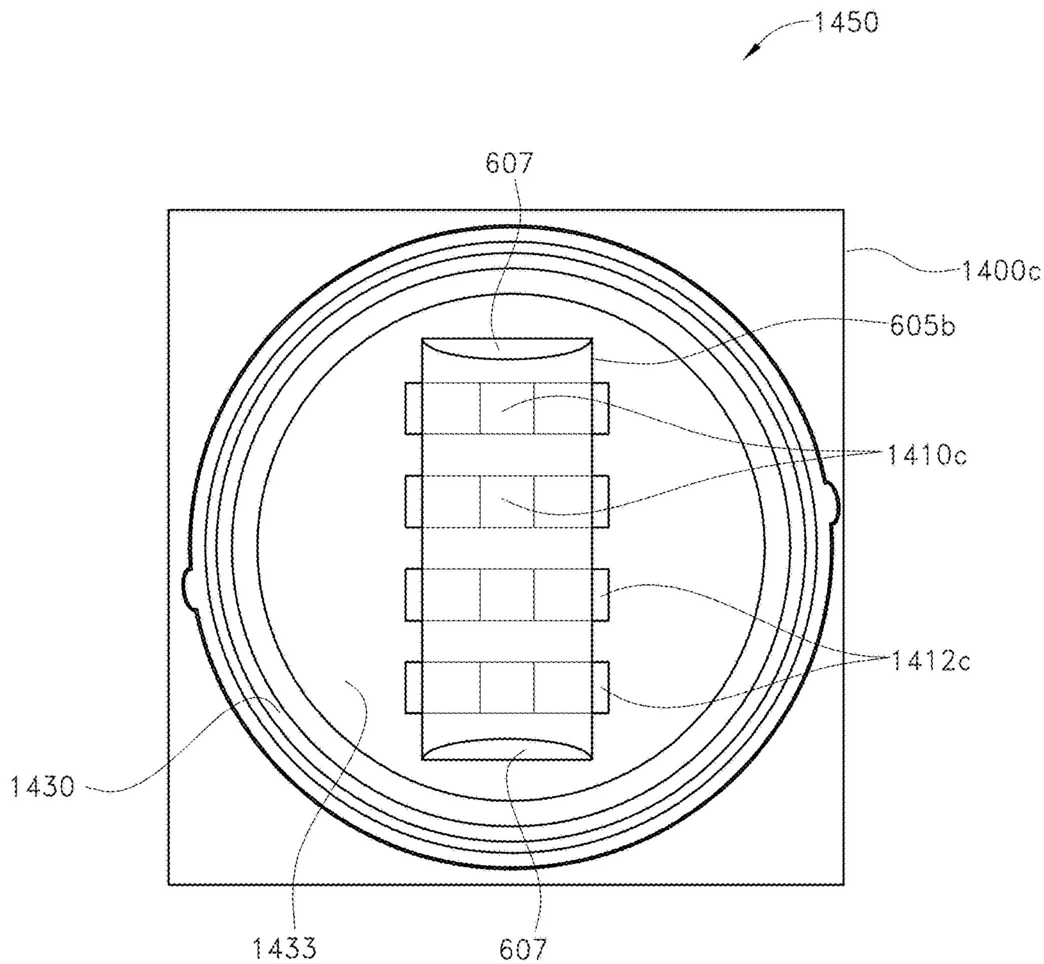


FIG. 14E

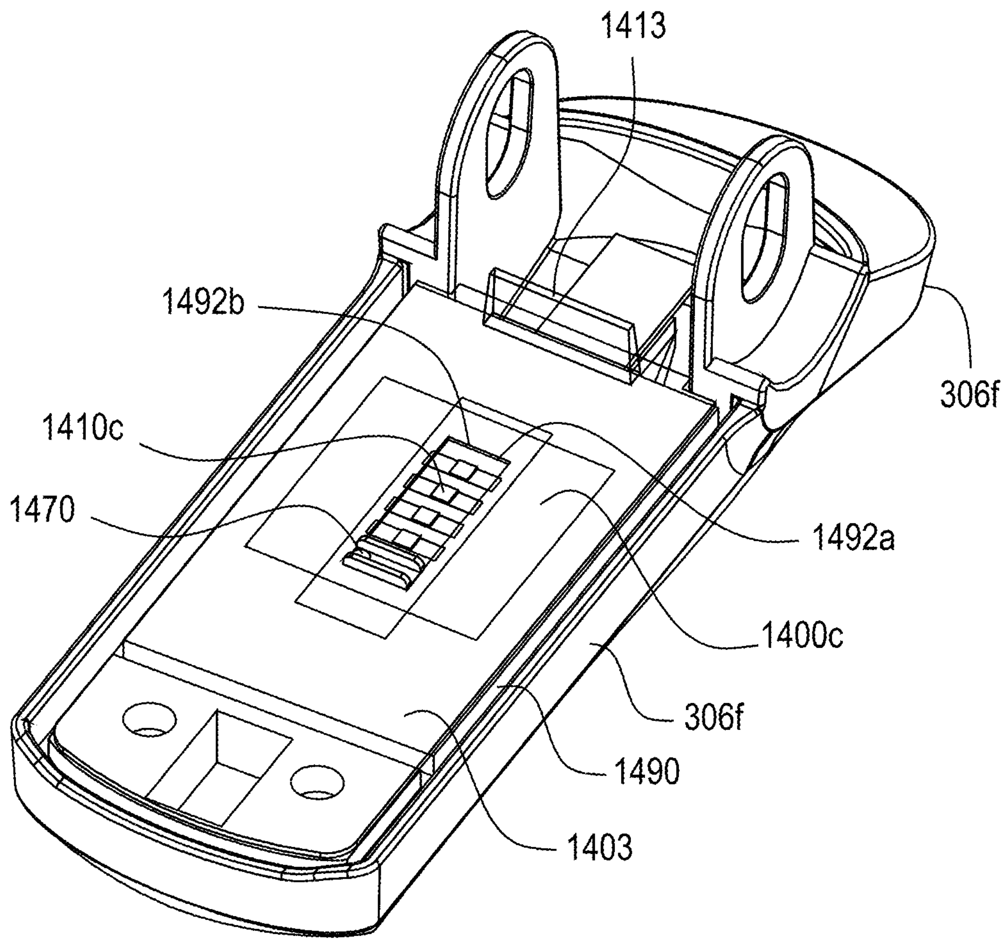


FIG. 14F

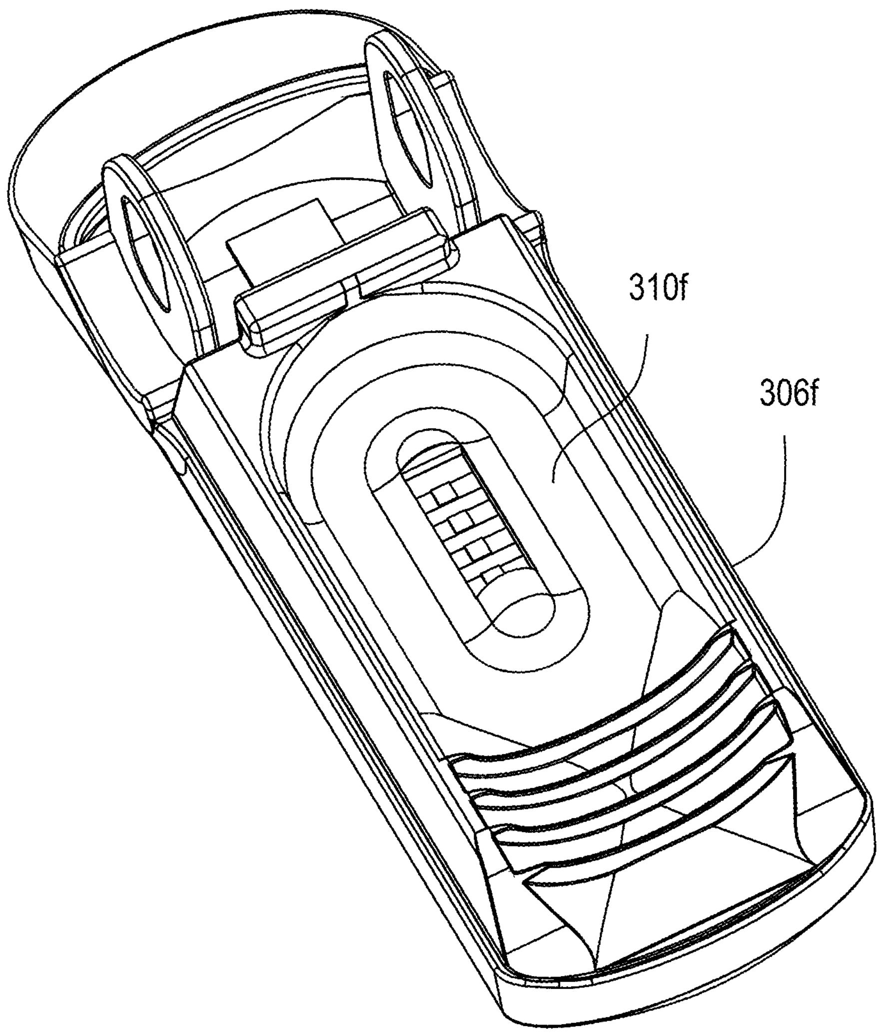


FIG. 14G

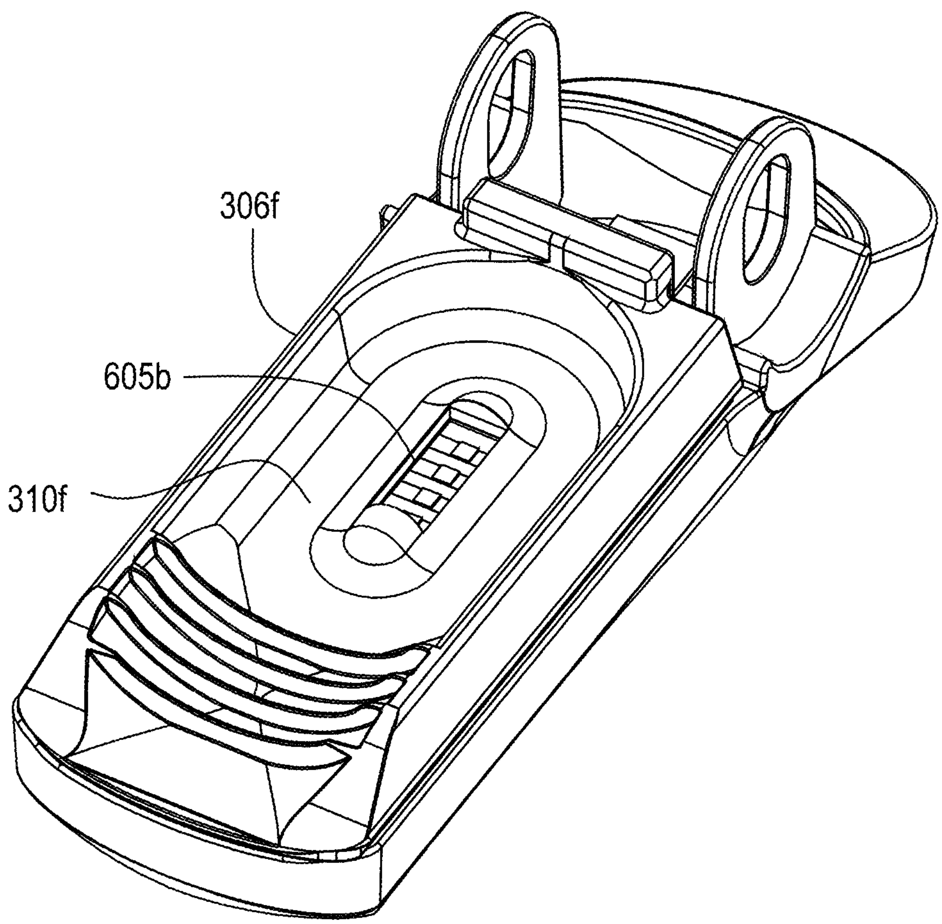


FIG. 14H

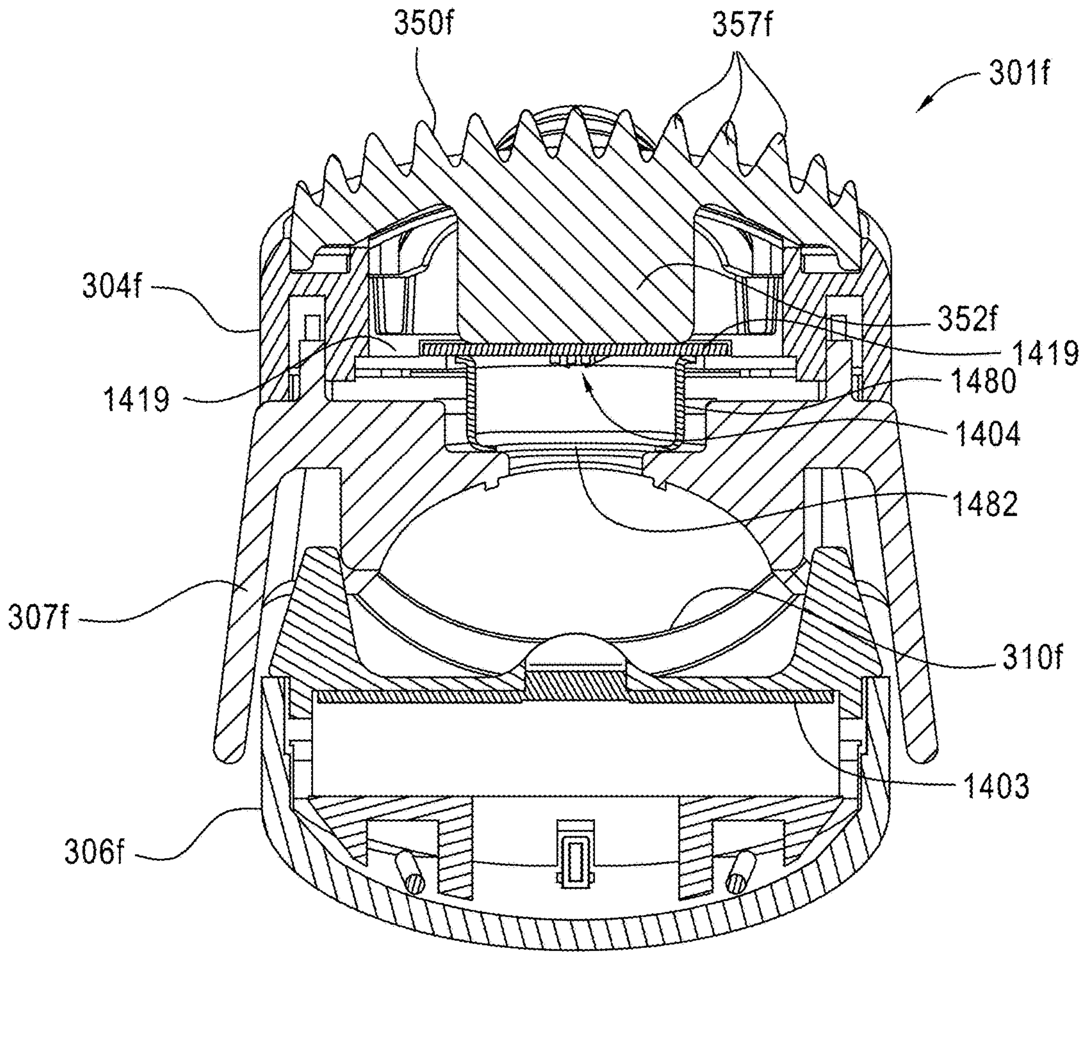
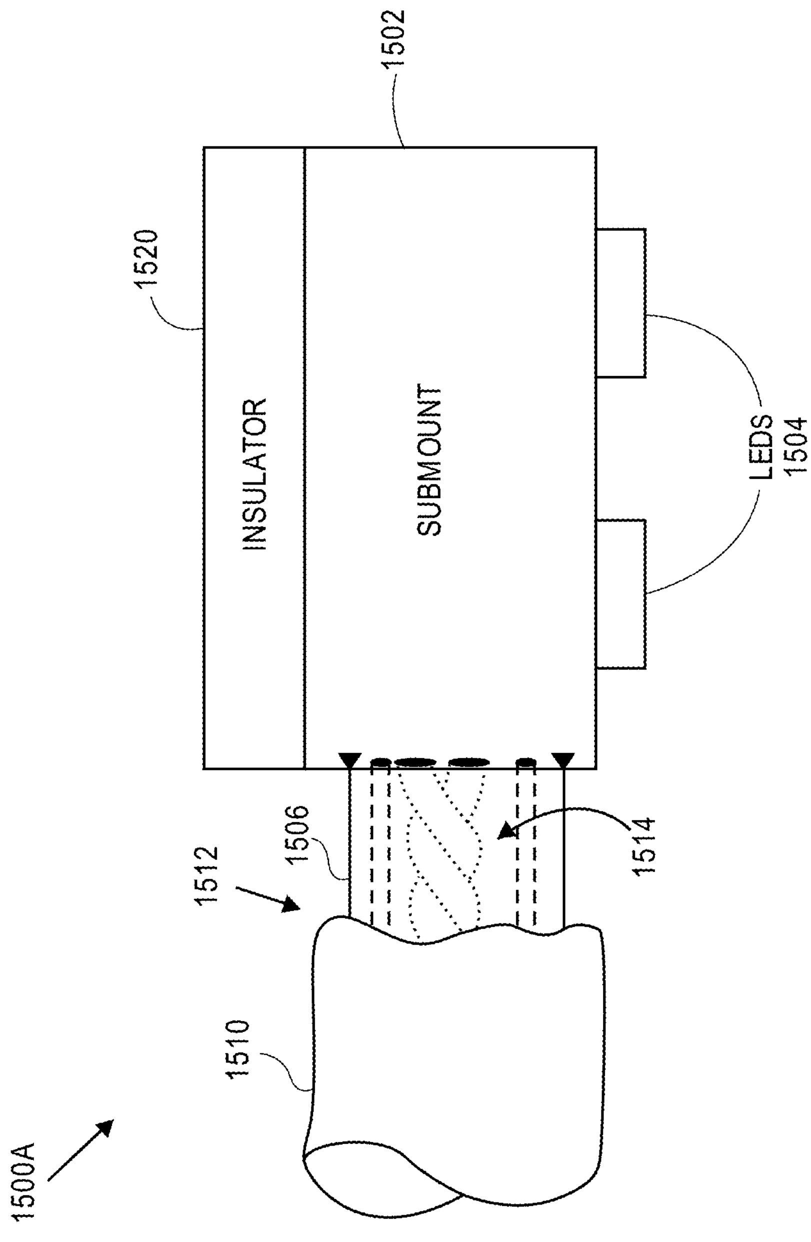

350f
357f
301f
304f
352f
1419
1419
1480
1404
1482
307f
310f
1403
306f

FIG. 14I



1502
1520
INSULATOR
SUBMOUNT
LEDS
1504
1506
1512
1514
1510
1500A

FIG. 15A

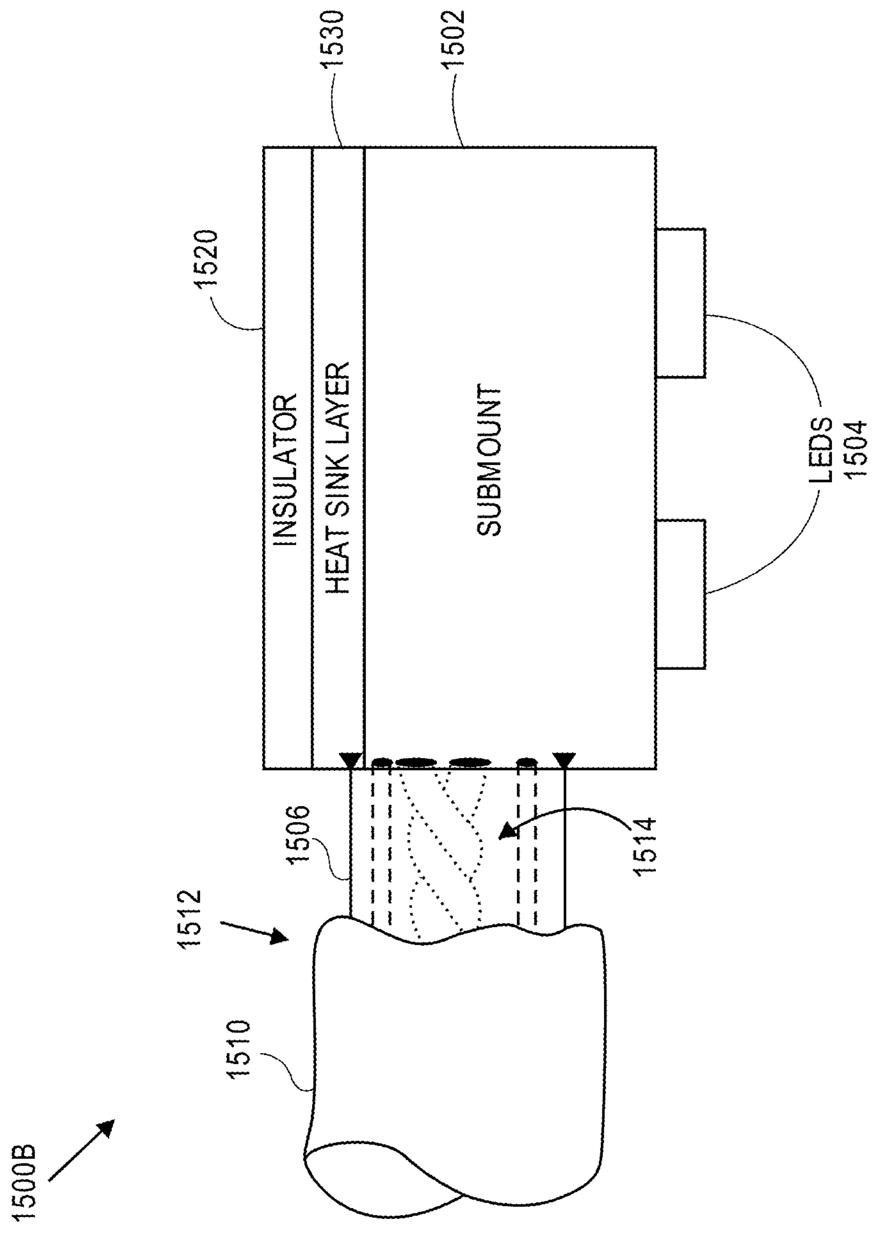

1530
1502
1520
INSULATOR
HEAT SINK LAYER
SUBMOUNT
LEDS
1504
1506
1514
1512
1510
1500B

FIG. 15B

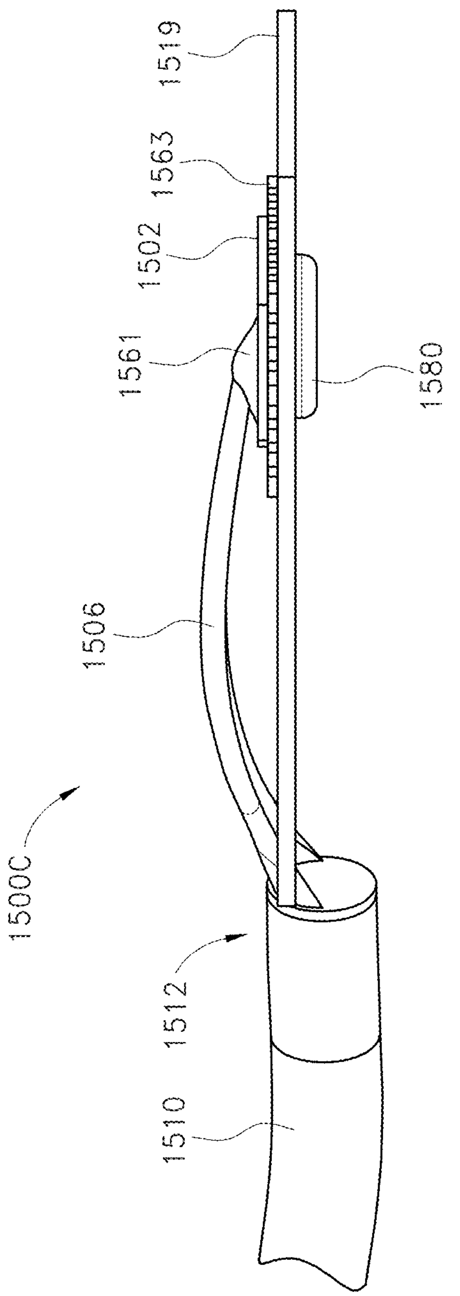


FIG. 15C

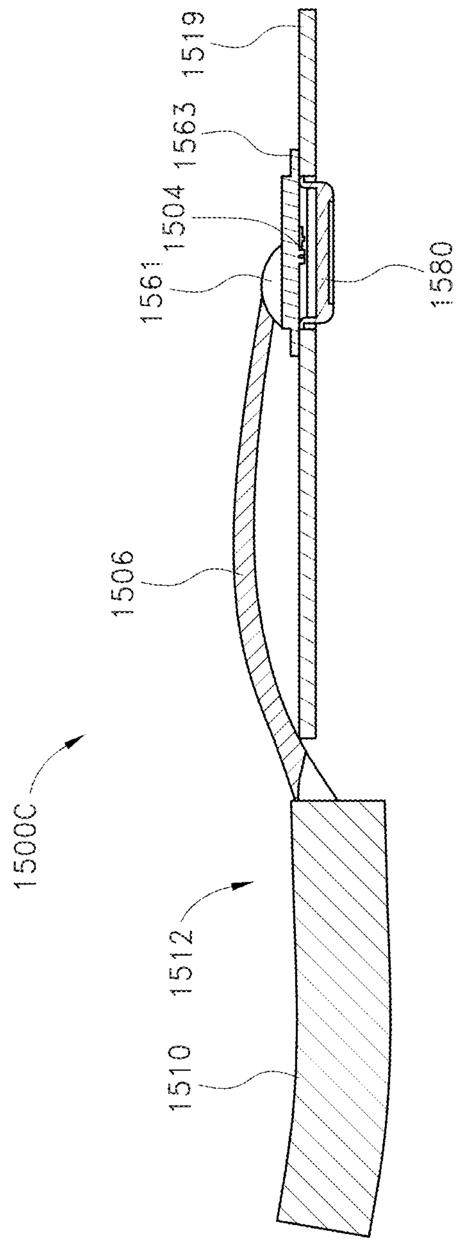


FIG. 15D

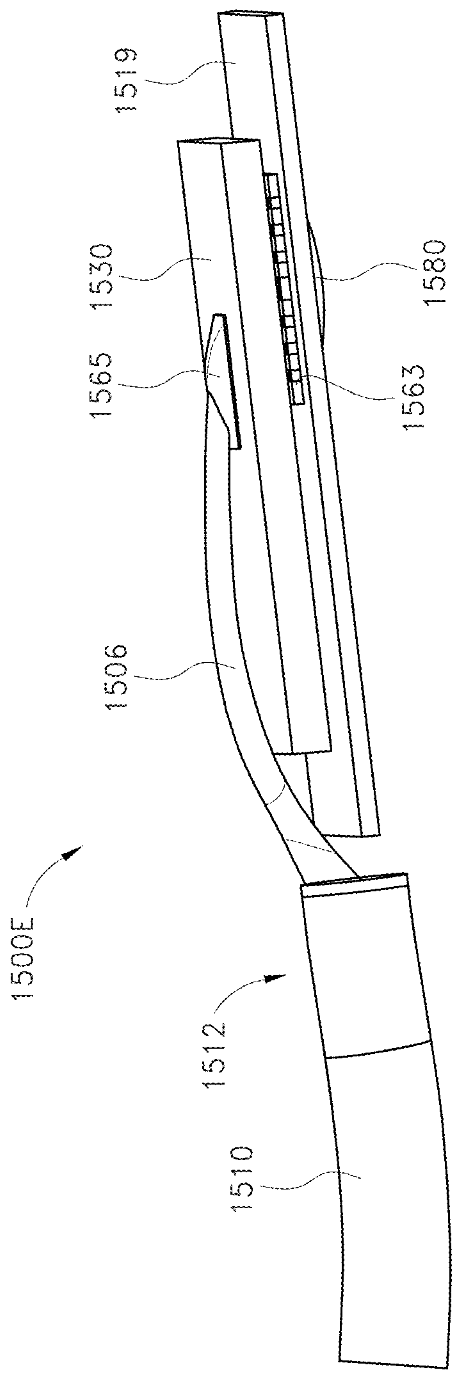


FIG. 15E

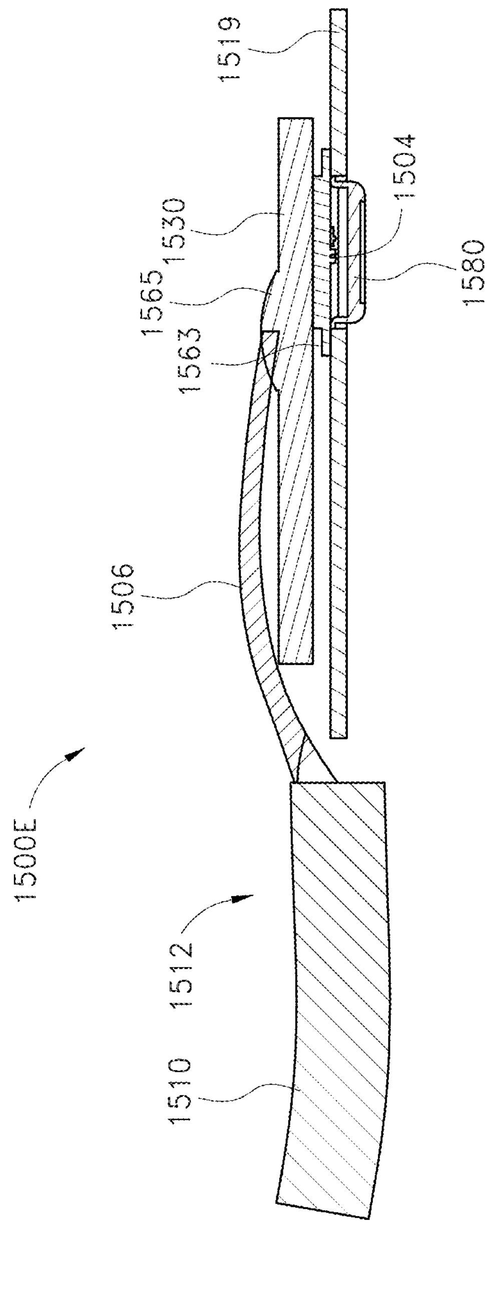


FIG. 15F

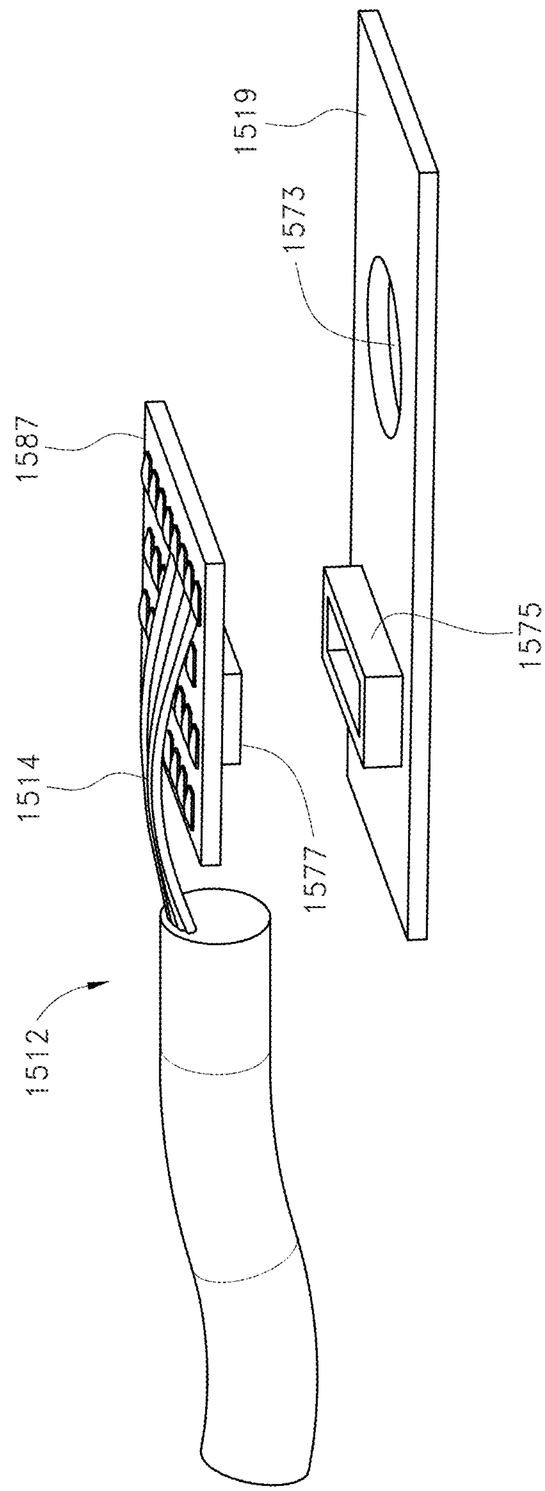


FIG. 15G

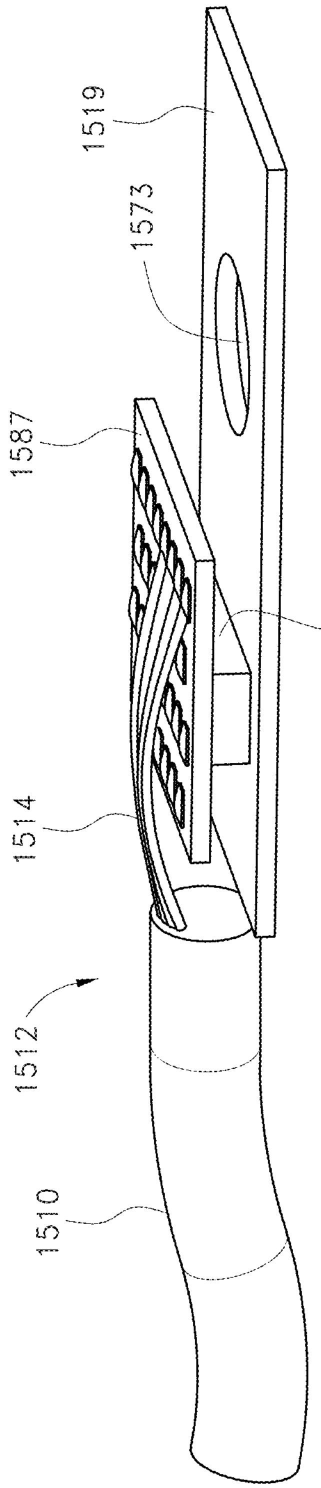


FIG. 15H

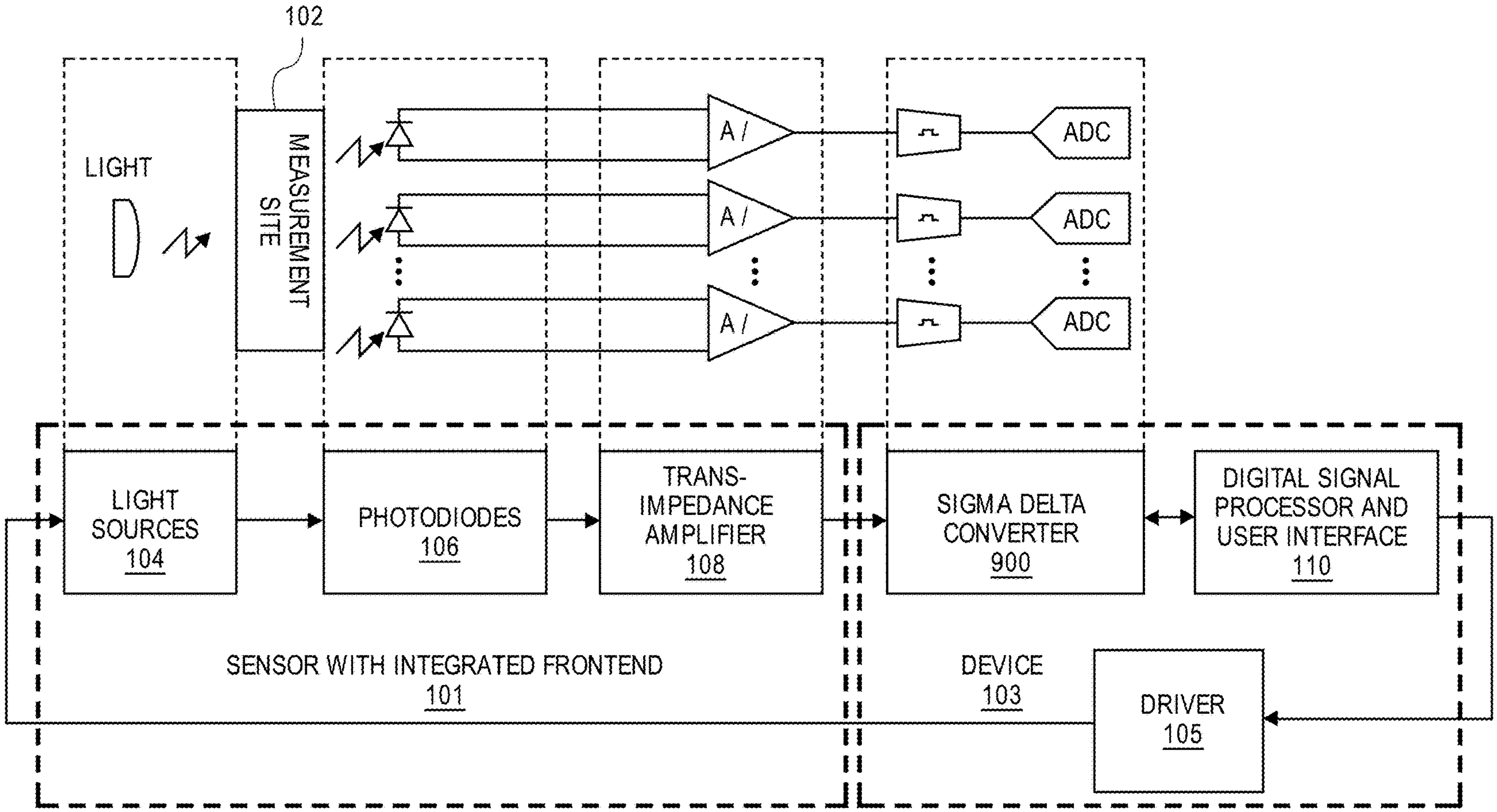

102
LIGHT
MEASUREMENT SITE
A /
A /
A /
ADC
ADC
ADC
LIGHT SOURCES 104
PHOTODIODES 106
TRANS-IMPEDANCE AMPLIFIER 108
SIGMA DELTA CONVERTER 900
DIGITAL SIGNAL PROCESSOR AND USER INTERFACE 110
SENSOR WITH INTEGRATED FRONTEND 101
DEVICE 103
DRIVER 105

FIG. 15I

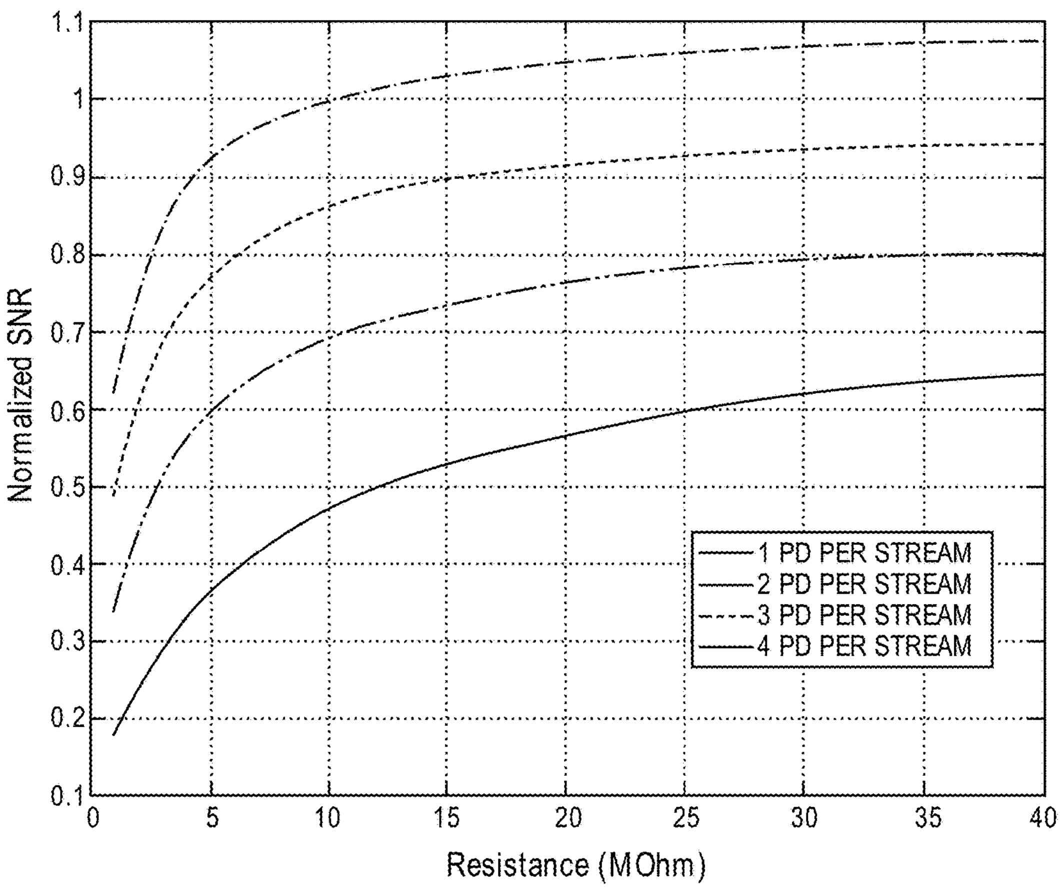

Normalized SNR
Resistance (MOhm)
1 PD PER STREAM
2 PD PER STREAM
3 PD PER STREAM
4 PD PER STREAM
0
5
10
15
20
25
30
35
40
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
1.1

FIG. 15J

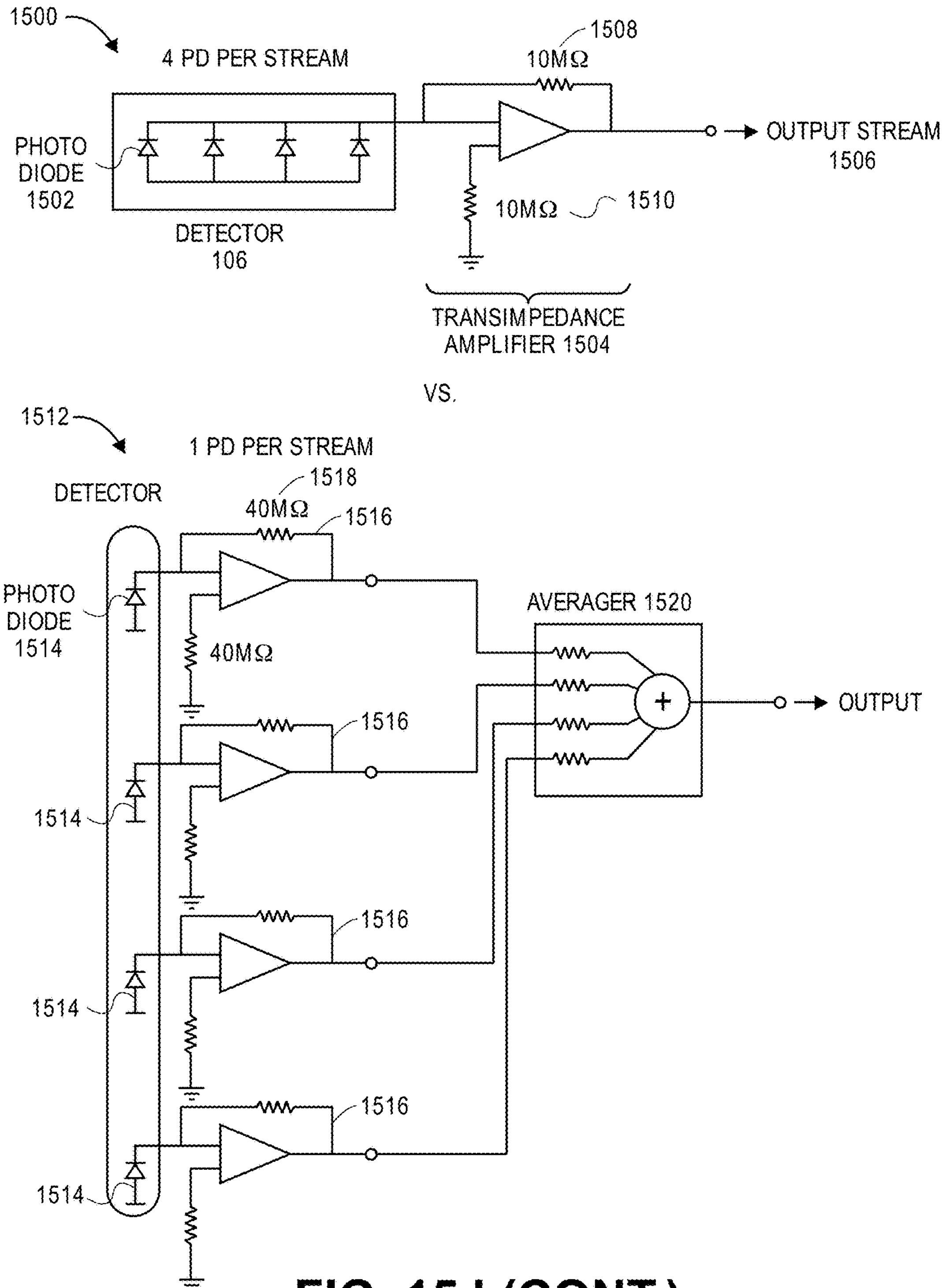
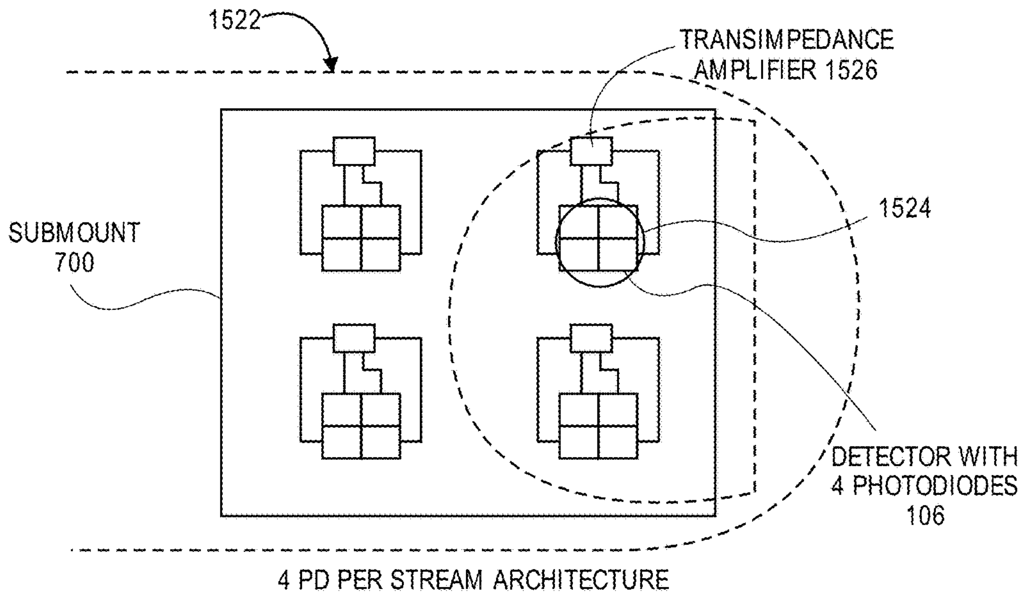

1500
4 PD PER STREAM
1508
10MΩ
PHOTO DIODE 1502
OUTPUT STREAM 1506
10MΩ
1510
DETECTOR 106
TRANSIMPEDANCE AMPLIFIER 1504
VS.
1512
1 PD PER STREAM
1518
DETECTOR
40MΩ
1516
PHOTO DIODE 1514
AVERAGER 1520
40MΩ
+
OUTPUT
1516
1514
1516
1514
1516
1514

FIG. 15J (CONT.)


1522
TRANSIMPEDANCE AMPLIFIER 1526
1524
SUBMOUNT 700
DETECTOR WITH 4 PHOTODIODES 106
4 PD PER STREAM ARCHITECTURE

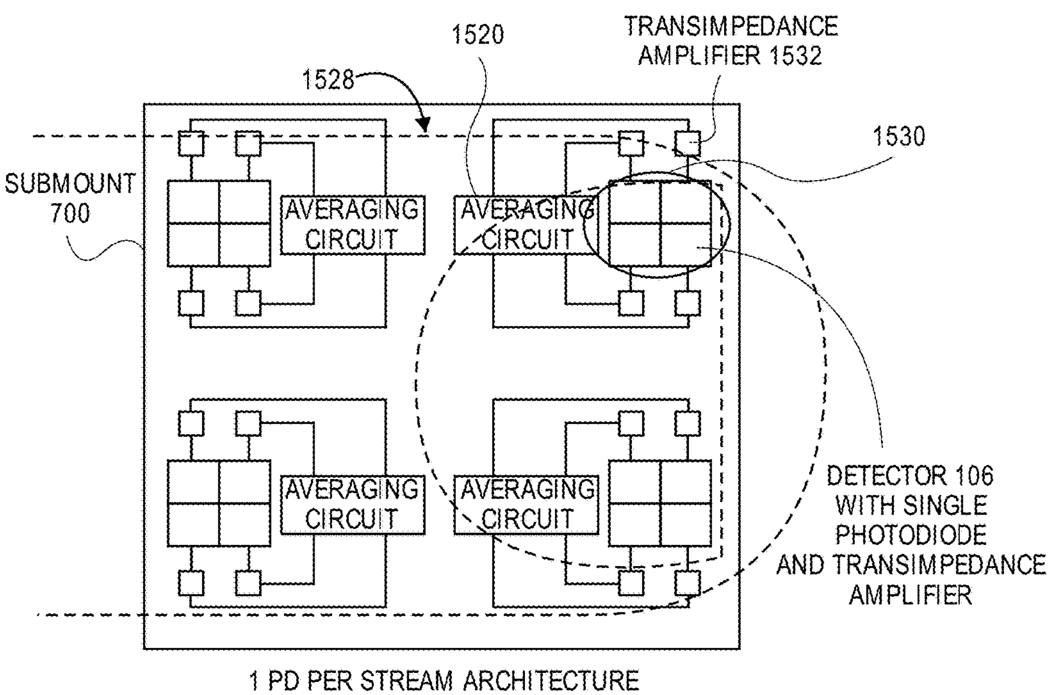
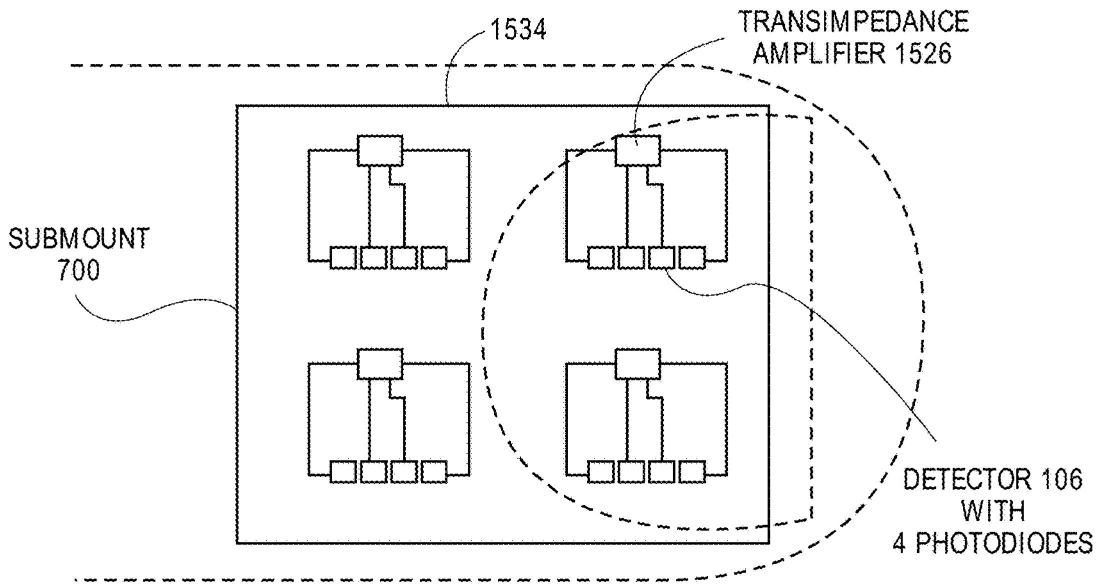
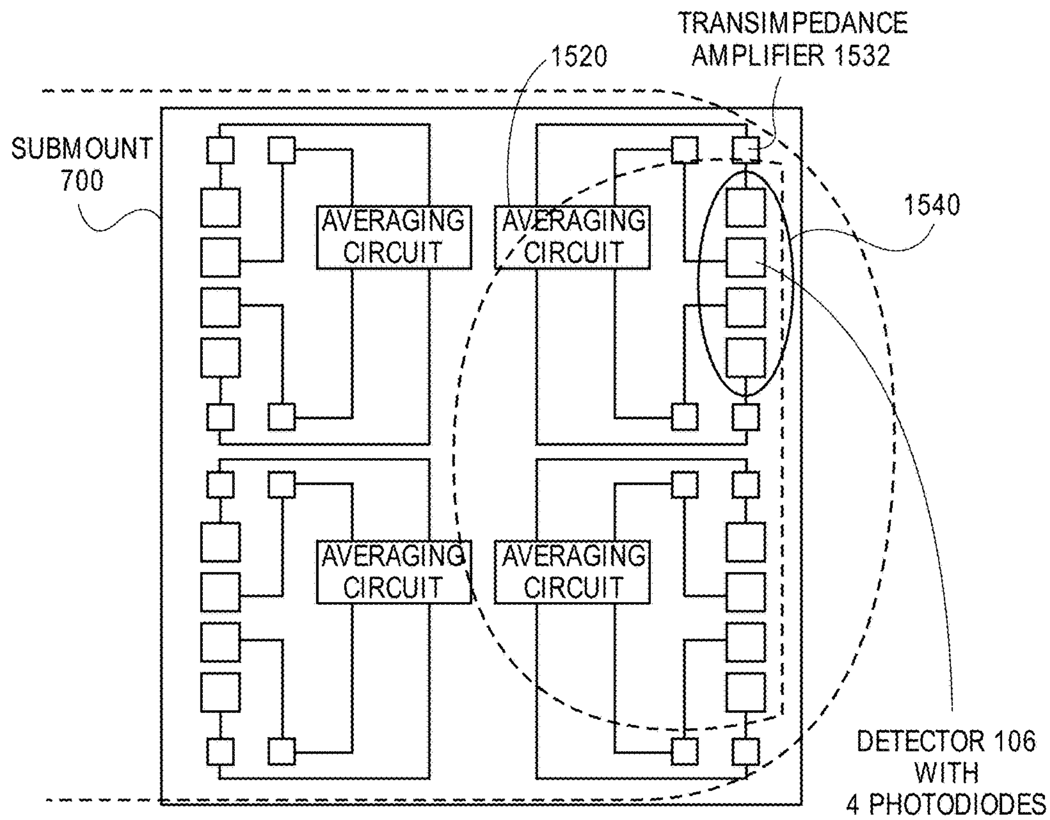

1520
TRANSIMPEDANCE AMPLIFIER 1532
1528
1530
SUBMOUNT 700
AVERAGING CIRCUIT
AVERAGING CIRCUIT
AVERAGING CIRCUIT
AVERAGING CIRCUIT
DETECTOR 106 WITH SINGLE PHOTODIODE AND TRANSIMPEDANCE AMPLIFIER
1 PD PER STREAM ARCHITECTURE

FIG. 15K

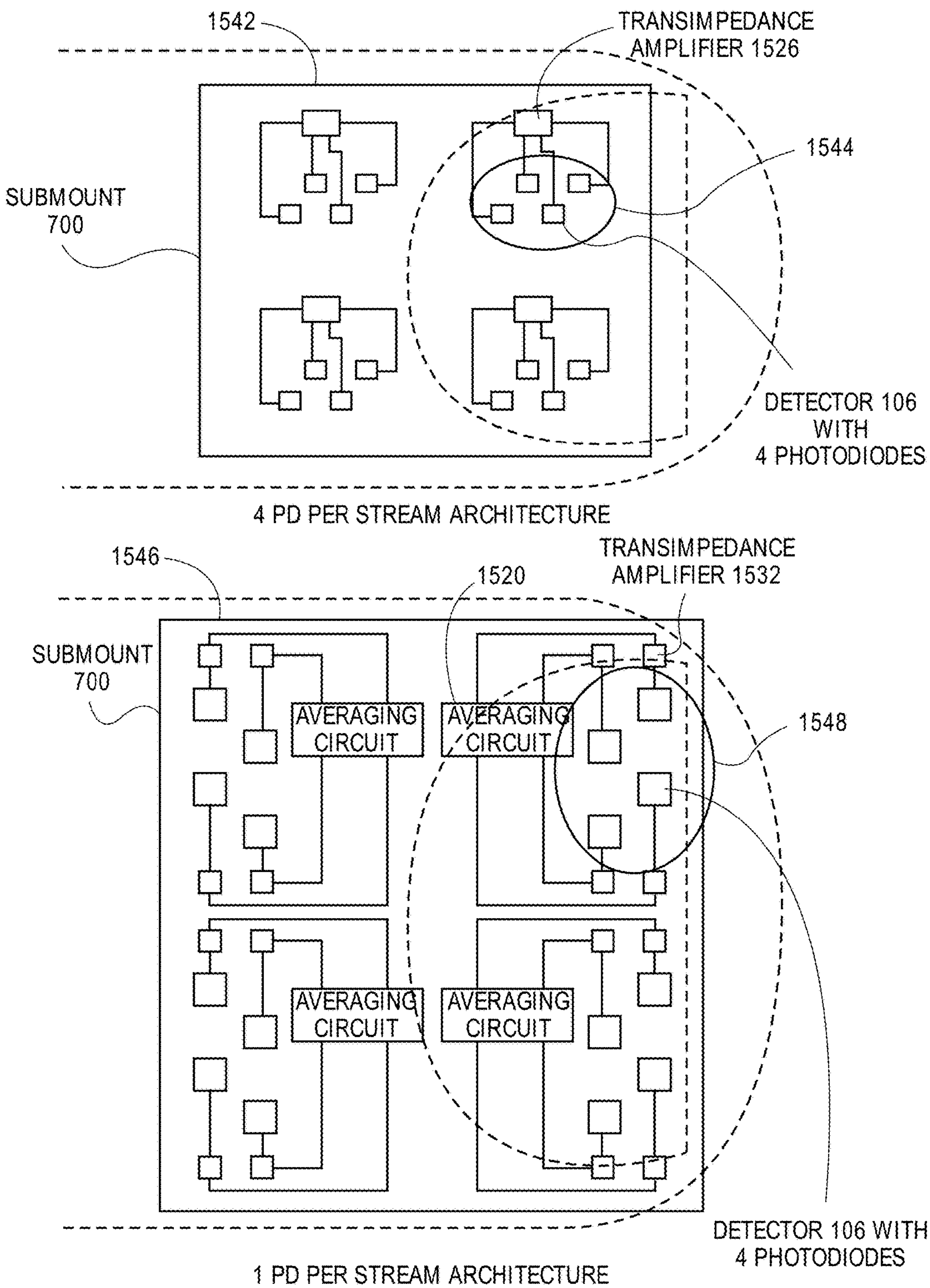


4 PD PER STREAM ARCHITECTURE



1 PD PER STREAM ARCHITECTURE

FIG. 15K (CONT.)



1542
TRANSIMPEDANCE AMPLIFIER 1526
1544
SUBMOUNT 700
DETECTOR 106 WITH 4 PHOTODIODES
4 PD PER STREAM ARCHITECTURE
1546
1520
TRANSIMPEDANCE AMPLIFIER 1532
SUBMOUNT 700
AVERAGING CIRCUIT
AVERAGING CIRCUIT
1548
AVERAGING CIRCUIT
AVERAGING CIRCUIT
DETECTOR 106 WITH 4 PHOTODIODES
1 PD PER STREAM ARCHITECTURE

FIG. 15K (CONT.)

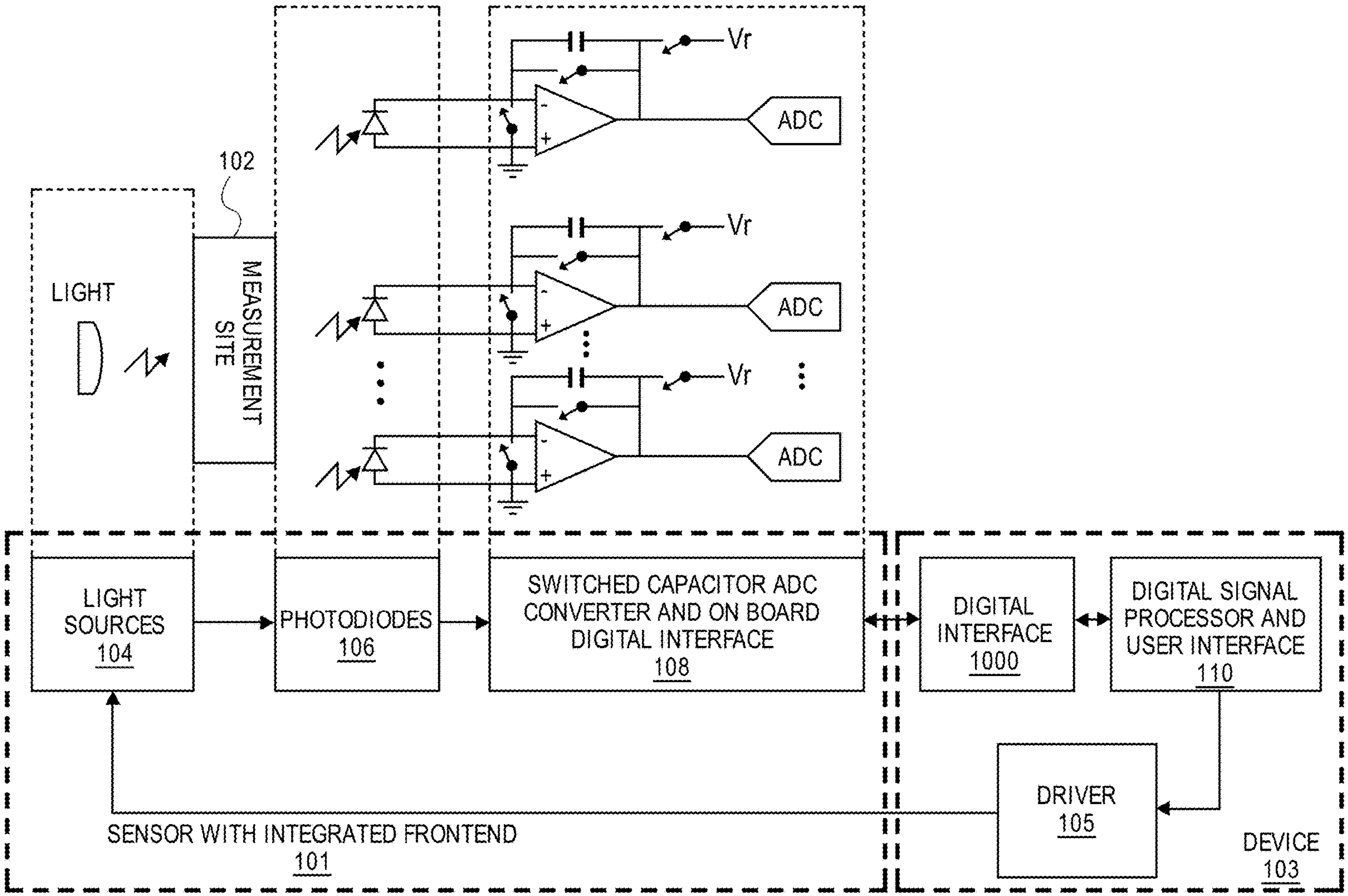

102
LIGHT
MEASUREMENT SITE
Vr
ADC
Vr
ADC
Vr
ADC
LIGHT SOURCES 104
PHOTODIODES 106
SWITCHED CAPACITOR ADC CONVERTER AND ON BOARD DIGITAL INTERFACE 108
DIGITAL INTERFACE 1000
DIGITAL SIGNAL PROCESSOR AND USER INTERFACE 110
DRIVER 105
SENSOR WITH INTEGRATED FRONTEND 101
DEVICE 103

FIG. 15L

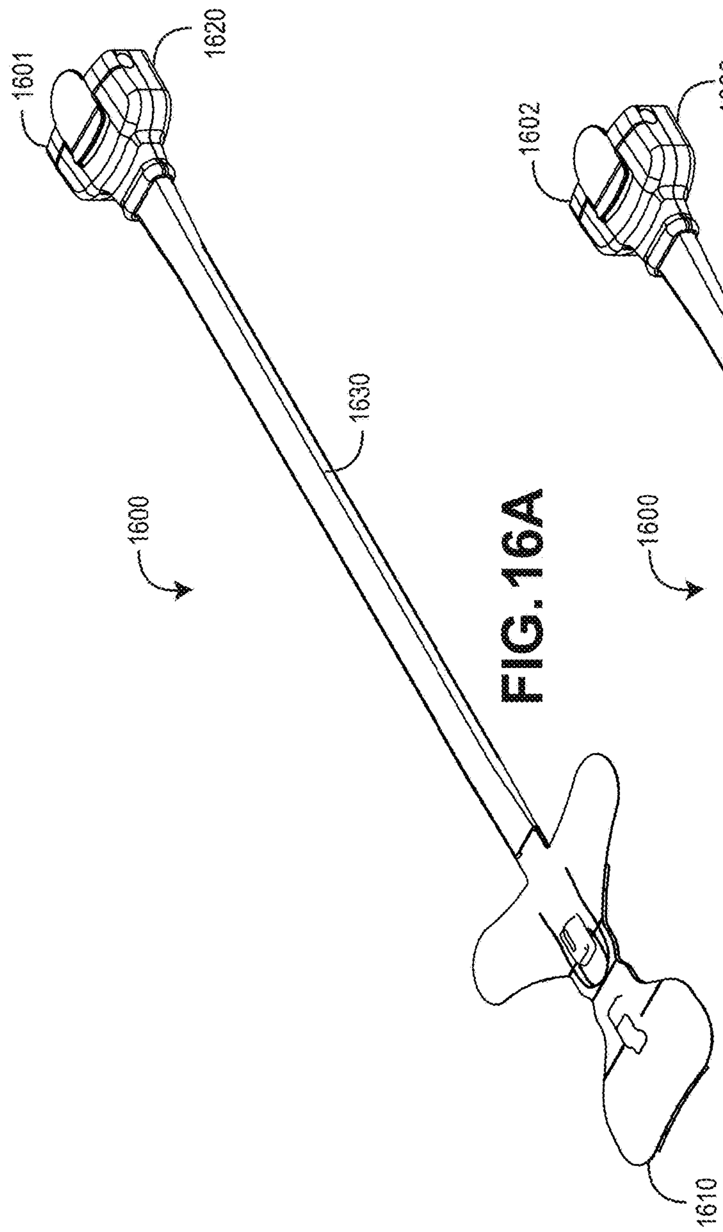


FIG. 16A

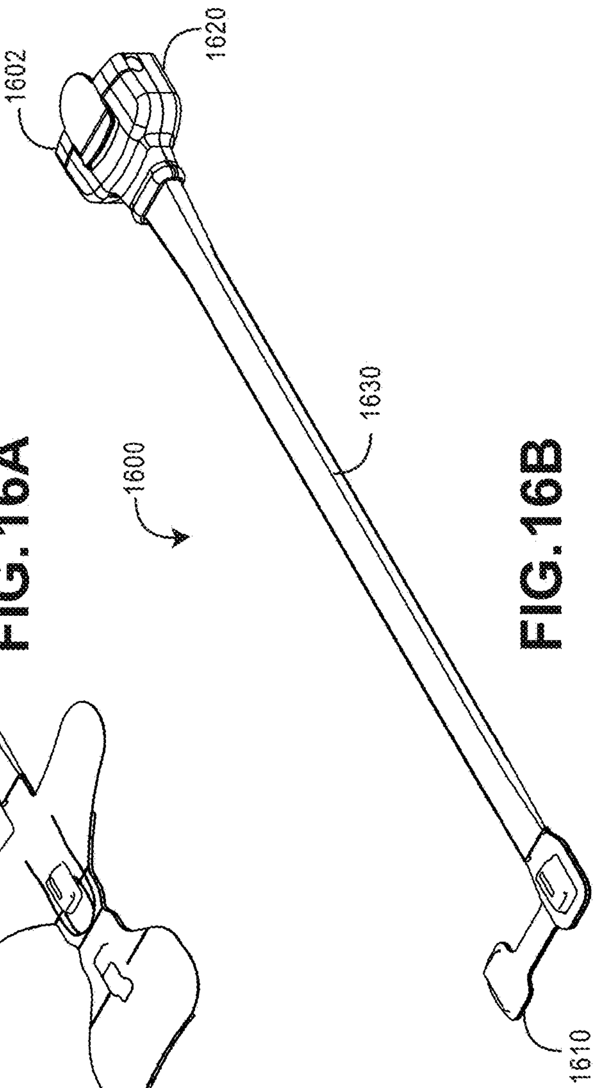


FIG. 16B

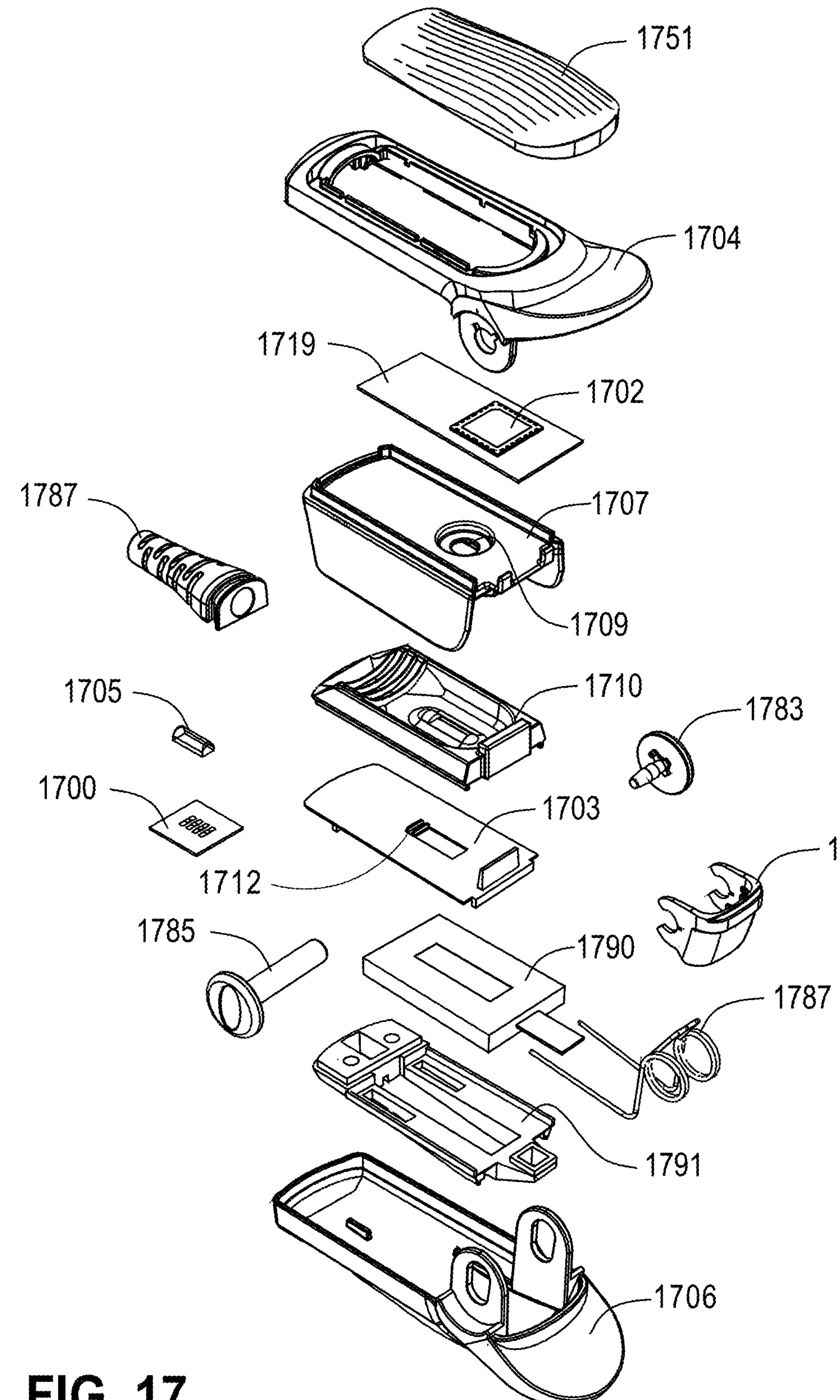
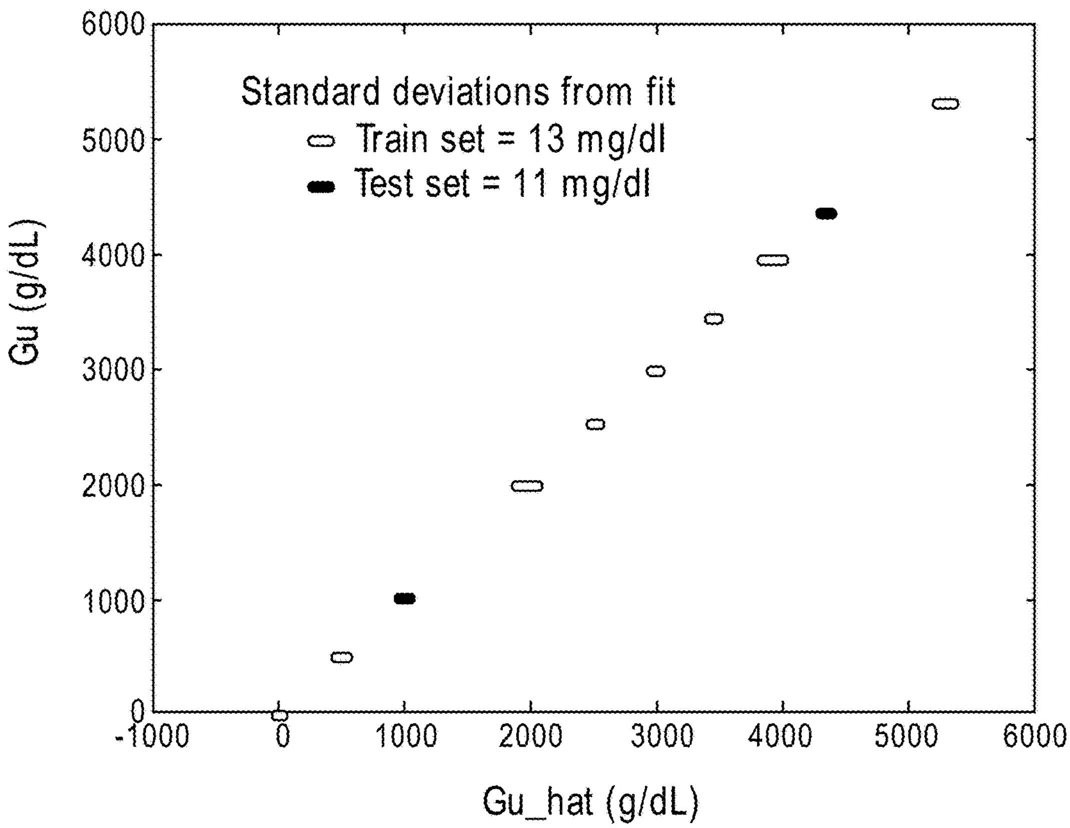

1751
1704
1719
1702
1787
1707
1709
1705
1710
1783
1700
1703
1712
1760
1785
1790
1787
1791
1706

FIG. 17



Standard deviations from fit
Train set = 13 mg/dl
Test set = 11 mg/dl
Gu (g/dL)
Gu_hat (g/dL)
6000
5000
4000
3000
2000
1000
0
-1000
0
1000
2000
3000
4000
5000
6000

FIG. 18

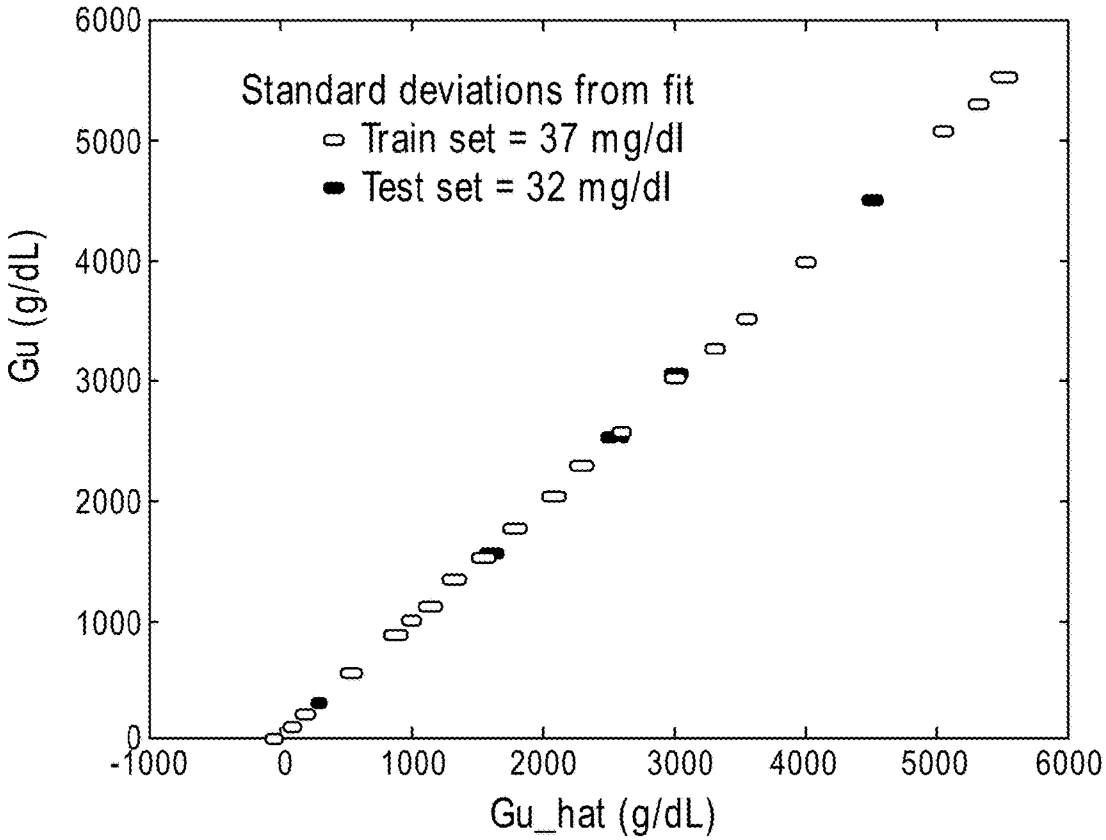

Standard deviations from fit
Train set = 37 mg/dl
Test set = 32 mg/dl
Gu (g/dL)
Gu_hat (g/dL)
6000
5000
4000
3000
2000
1000
0
-1000
0
1000
2000
3000
4000
5000
6000

FIG. 19

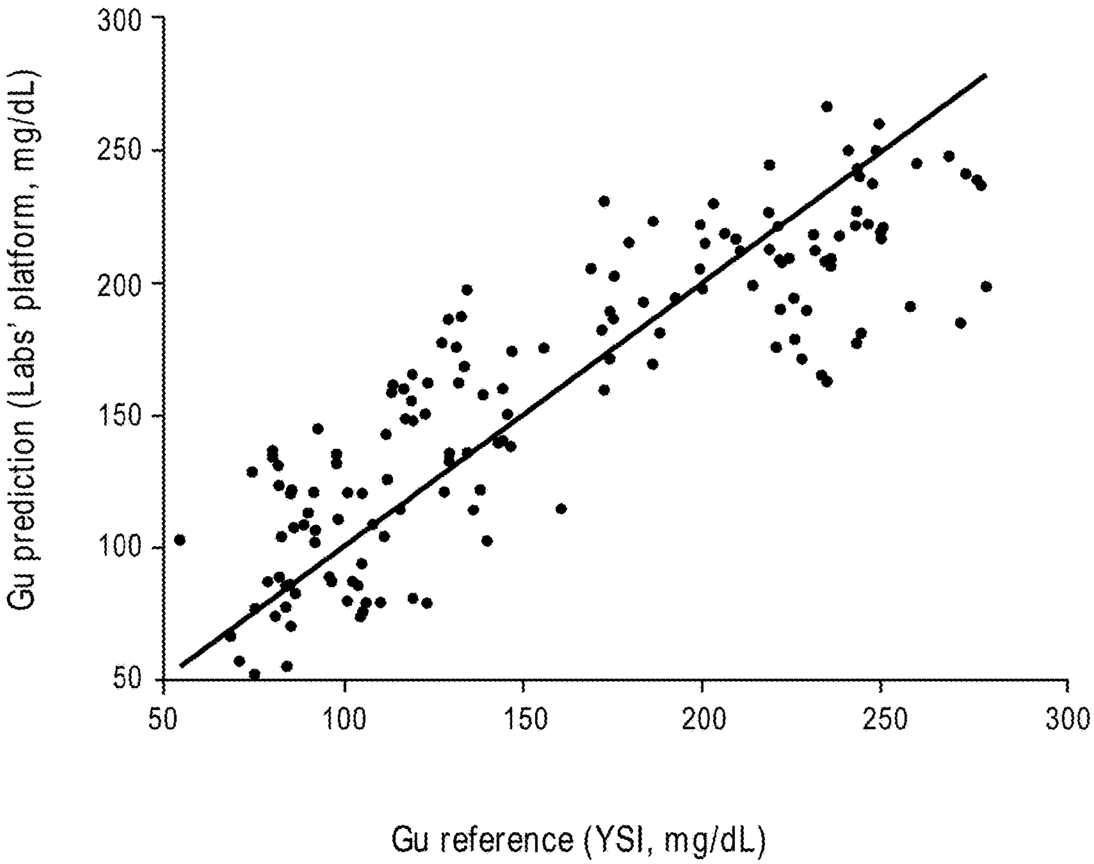
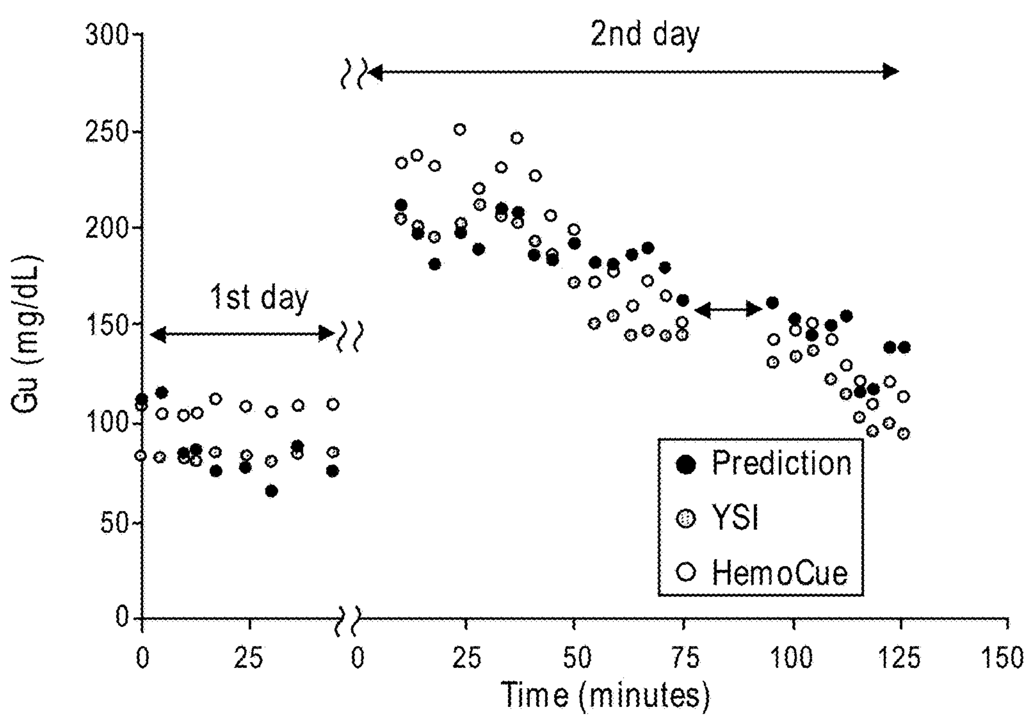

300
250
200
150
100
50
Gu prediction (Labs' platform, mg/dL)
50
100
150
200
250
300
Gu reference (YSI, mg/dL)

FIG. 20



2nd day
1st day
300
250
200
150
100
50
0
Gu (mg/dL)
0
25
0
25
50
75
100
125
150
Time (minutes)
Prediction
YSI
HemoCue

FIG. 21

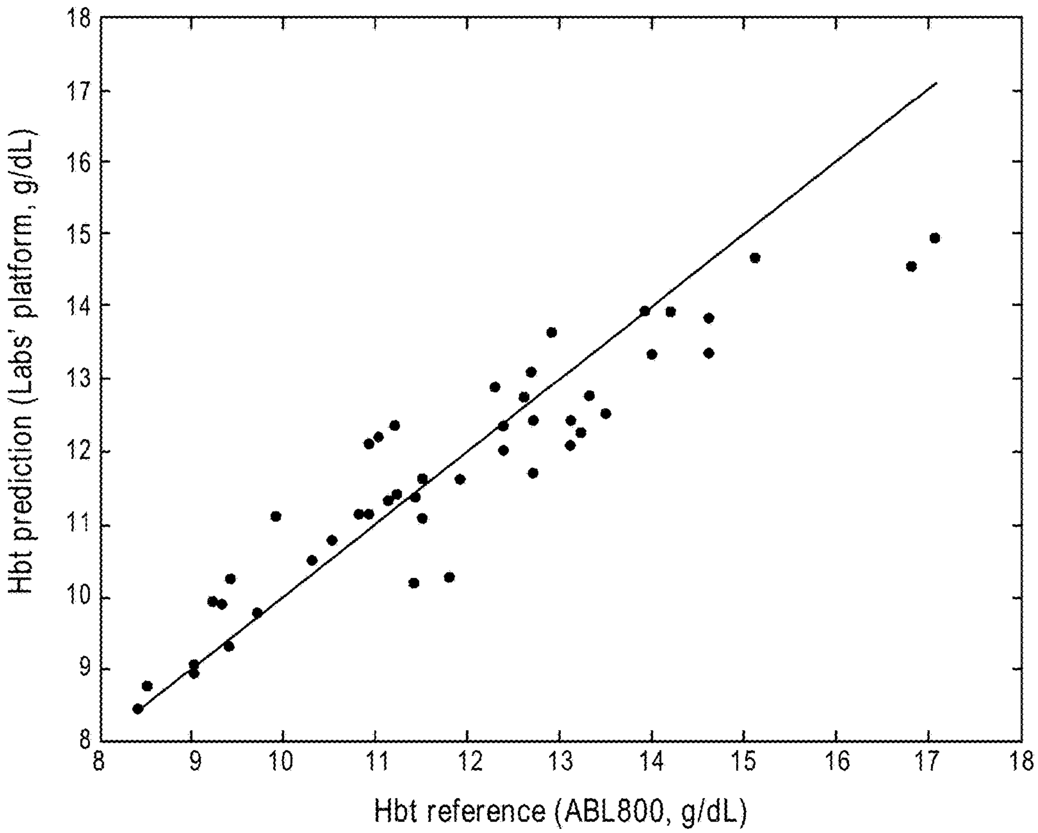

Hbt prediction (Labs' platform, g/dL)
Hbt reference (ABL800, g/dL)
8
9
10
11
12
13
14
15
16
17
18

FIG. 22

MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. Patent Applications:

Application Ser. No.	Filing Date	Title
12/497,528	Jul. 2, 2009	Noise Shielding for Noninvasive Device
12/497,523	Jul. 2, 2009	Contoured Protrusion for Improving Spectroscopic Measurement of Blood Constituents
12/497,506	Jul. 2, 2009	Heat Sink for Noninvasive Medical Sensor
12/534,812	Aug. 3, 2009	Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents
12/534,823	Aug. 3, 2009	Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents
12/534,825	Aug. 3, 2009	Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents

The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photodetection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal(s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the noninvasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from said optical source after attenuation by the tissue of the measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least

some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the signals from the plurality of detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be re-used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. **1** illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. **2**A-**2**D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. **1**, according to embodiments of the disclosure;

FIGS. **3**A-**3**C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. **3**D illustrates a side view of another example non-invasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. **3**E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. **3**F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. **4**A through **4**C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

FIG. **5** illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

FIGS. **6**A through **6**D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. **6**E illustrates an example sensor incorporating the protrusion of FIGS. **6**A through **6**D, according to an embodiment of the disclosure;

FIGS. **7**A through **7**B illustrate example arrangements of conductive glass that may be employed in the system of FIG. **1**, according to embodiments of the disclosure;

FIGS. **8**A through **8**D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. **1**, according to embodiments of the disclosure;

FIG. **9** shows example comparative results obtained by an embodiment of a sensor;

FIGS. **10**A and **10**B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. **11**A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. **11**B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. **11**C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. **11**D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. **12**A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. **12**B through **12**D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. **12**E through **12**H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. **13** illustrates an example multi-stream operation of the system of FIG. **1**, according to an embodiment of the disclosure;

FIG. **14**A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. **14**B depicts a front elevation view of the partially cylindrical protrusion of FIG. **14**A;

FIGS. **14**C through **14**E illustrate embodiments of a detector submount;

FIGS. **14**F through **14**H illustrate embodiment of portions of a detector shell;

FIG. **14**I illustrates a cutaway view of an embodiment of a sensor;

FIGS. **15**A through **15**F illustrate embodiments of sensors that include heat sink features;

FIGS. **15**G and **15**H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. **15**I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

FIG. **15**J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. **15**I;

FIG. **15**K shows different architectures and layouts for various embodiments of a sensor and its detectors;

FIG. **15**L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. **16**A and **16**B illustrate embodiments of disposable optical sensors;

FIG. **17** illustrates an exploded view of certain components of an example sensor; and

FIGS. **18** through **22** illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of noninvasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metalicized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that, in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modi-

fications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. **1** illustrates an example of a data collection system **100**. In certain embodiments, the data collection system **100** noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system **100** can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system **100** can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system **100** can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm^2-5 mm^2 (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system **100** can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system **100** can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system **100** can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system **100** can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site **102**. The measurement site **102** can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a finger measurement site **102**. However, the features of the embodiments disclosed herein can be used with other measurement sites **102**.

In the depicted embodiment, the system **100** includes an optional tissue thickness adjuster or tissue shaper **105**, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper **105** is a flat or substantially flat surface that can be positioned proximate the measurement site **102** and that can apply sufficient pressure to cause the tissue of the measurement site **102** to be flat or substantially flat. In other embodiments, the tissue shaper **105** is a convex or substantially convex surface with respect to the measurement site **102**. Many other configurations of the tissue shaper

105 are possible. Advantageously, in certain embodiments, the tissue shaper **105** reduces thickness of the measurement site **102** while preventing or reducing occlusion at the measurement site **102**. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system **100** shown also includes an optional noise shield **103**. In an embodiment, the noise shield **103** can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site **102** to one or more detectors **106** (described below). For example, the noise shield **103** can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor **101** or electrically grounded. In an embodiment where the noise shield **103** includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site **102** is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system **100** can be used on a person's non-dominant hand or arm.

The data collection system **100** can include a sensor **101** (or multiple sensors) that is coupled to a processing device or physiological monitor **109**. In an embodiment, the sensor **101** and the monitor **109** are integrated together into a single unit. In another embodiment, the sensor **101** and the monitor **109** are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor **101** and monitor **109** can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor **101** and the monitor **109** will now be further described.

In the depicted embodiment shown in FIG. **1**, the sensor **101** includes an emitter **104**, a tissue shaper **105**, a set of detectors **106**, and a front-end interface **108**. The emitter **104** can serve as the source of optical radiation transmitted towards measurement site **102**. As will be described in further detail below, the emitter **104** can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **104** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter **104** is used as a point optical source, and thus, the one or more optical sources of the emitter **104** can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters **104** can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters **104** can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters **104**.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter **104** of the data collection system **100** can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter **104** can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter **104** can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter **104** can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter **104** can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter **104** can emit optical radiation across other spectra for other analytes. In particular, the emitter **104** can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter **104** can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter **104** can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, the emitter **104** can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system **100** can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water

from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter **104** can include sets of light-emitting diodes (LEDs) as its optical source. The emitter **104** can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter **104** can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter **104** can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter **104** can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter **104** can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO_2), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter **104** can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site **102**.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter **104** can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter **104** to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system **100** also includes a driver **111** that drives the emitter **104**. The driver **111** can be a circuit or the like that is controlled by the monitor **109**. For example, the driver **111** can provide pulses of current to the emitter **104**. In an embodiment, the driver **111** drives the emitter **104** in a progressive fashion, such as in an alternating manner. The driver **111** can drive the emitter **104** with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

The driver **111** can be synchronized with other parts of the sensor **101** and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter **104**. In some embodiments, the driver **111** is capable of driving the emitter **104** to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors **106** capture and measure light from the measurement site **102**. For example, the detectors **106** can capture and measure light transmitted from the emitter **104** that has been attenuated or reflected from the tissue in the measurement site **102**. The detectors **106** can output a detector signal **107** responsive to the light captured or measured. The detectors **106** can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors **106** can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors **106**. That is, some of the detectors **106** can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter **104**. However, according to an embodiment, at least some of the detectors **106** can have a different path length from the emitter **104** relative to other of the detectors **106**. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors **106**. In some embodiments, the detectors **106** may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface **108** provides an interface that adapts the output of the detectors **106**, which is responsive to desired physiological parameters. For example, the front end interface **108** can adapt a signal **107** received from one or more of the detectors **106** into a form that can be processed by the monitor **109**, for example, by a signal processor **110** in the monitor **109**. The front end interface **108** can have its components assembled in the sensor **101**, in the monitor **109**, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface **108** can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface **108** can be coupled to the detectors **106** and to the signal processor **110** using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface **108** can also be at least partially integrated with various components, such as the detectors **106**. For example, the front end interface **108** can include one or more integrated circuits that are on the same circuit board as the detectors **106**. Other configurations can also be used.

The front end interface **108** can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor **109**), such as a sigma-delta ADC. A transimpedance-based front end interface **108** can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface **108** can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface **108** can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter **104**.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by the signal processor **110** of the monitor **109**. Each channel can correspond to a signal output from a detector **106**.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface **108**. For example, the output of a transimpedance-based front end interface **108** can be output to a PGA that is coupled with an ADC in the monitor **109**. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the

detectors **106**. Alternatively, the PGA and ADC components can be integrated with the transimpedance-based front end interface **108** in the sensor **101**.

In another embodiment, the front end interface **108** can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface **108** can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface **108** can be useful because it can provide a digital signal to the signal processor **110** in the monitor **109**.

As shown in FIG. **1**, the monitor **109** can include the signal processor **110** and a user interface, such as a display **112**. The monitor **109** can also include optional outputs alone or in combination with the display **112**, such as a storage device **114** and a network interface **116**. In an embodiment, the signal processor **110** includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors **106**. The signal processor **110** can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor **110** can provide various signals that control the operation of the sensor **101**. For example, the signal processor **110** can provide an emitter control signal to the driver **111**. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter **104**. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter **104** to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface **108** is used, the control signal from the signal processor **110** can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory **113** can be included in the front-end interface **108** and/or in the signal processor **110**. This memory **113** can serve as a buffer or storage location for the front-end interface **108** and/or the signal processor **110**, among other uses.

The user interface **112** can provide an output, e.g., on a display, for presentation to a user of the data collection system **100**. The user interface **112** can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface **112** can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface **112** can include a flip screen, a screen that can be moved from one side to another on the monitor **109**, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data collection system **100** can be provided without a user interface **112** and can simply provide an output signal to a separate display or system.

A storage device **114** and a network interface **116** represent other optional output connections that can be included in the monitor **109**. The storage device **114** can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device **114**, which can be executed by the signal processor **110** or another processor of the monitor **109**. The network interface **116** can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor **109** to communicate and share data with other devices. The monitor **109** can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface **112**, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system **100** can include various other components or can be configured in different ways. For example, the sensor **101** can have both the emitter **104** and detectors **106** on the same side of the measurement site **102** and use reflectance to measure analytes. The data collection system **100** can also include a sensor that measures the power of light emitted from the emitter **104**.

FIGS. **2**A through **2**D illustrate example monitoring devices **200** in which the data collection system **100** can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices **200** shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system **100**. In addition, certain of the features of the monitoring devices **200** shown in FIGS. **2**A through **2**D can be combined with features of the other monitoring devices **200** shown.

Referring specifically to FIG. **2**A, an example monitoring device **200**A is shown, in which a sensor **201***a* and a monitor **209***a* are integrated into a single unit. The monitoring device **200**A shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor **201***a* includes an emitter shell **204***a* and a detector shell **206***a*. The depicted embodiment of the monitoring device **200**A also includes various control buttons **208***a* and a display **210***a*.

The sensor **201***a* can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector **106** by forcing light back into the sensor **201***a*. Pads in the emitter shell **204***a* and the detector shell **206***a* can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell **204***a* and the detector shell **206***a* can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor **201***a*.

In some embodiments, some or all portions of the emitter shell **204***a* and/or detector shell **206***a* can be detachable and/or disposable. For example, some or all portions of the shells **204***a* and **206***a* can be removable pieces. The removability of the shells **204***a* and **206***a* can be useful for sanitary purposes or for sizing the sensor **201***a* to different patients. The monitor **209***a* can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor **201***c* to be removably attached to the monitor **209***a*.

The monitoring device **200***a* also includes optional control buttons **208***a* and a display **210***a* that can allow the user to control the operation of the device. For example, a user can operate the control buttons **208***a* to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons **208***a* to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many

parameters, trends, alarms and parameter displays could be output to the display **210***a*, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls **208***a* and/or display **210***a* can provide functionality for the user to manipulate settings of the monitoring device **200***a*, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device **200***a* can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. **2**B illustrates another example of a monitoring device **200**B. In the depicted embodiment, the monitoring device **200**B includes a finger clip sensor **201***b* connected to a monitor **209***b* via a cable **212**. In the embodiment shown, the monitor **209***b* includes a display **210***b*, control buttons **208***b* and a power button. Moreover, the monitor **209***b* can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor **201***b*, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable **212** connecting the sensor **201***b* and the monitor **209***b* can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable **212** can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor **201***b* to the monitor **209***b*. Various lengths of the cable **212** can be employed to allow for separation between the sensor **201***b* and the monitor **209***b*. The cable **212** can be fitted with a connector (male or female) on either end of the cable **212** so that the sensor **201***b* and the monitor **209***b* can be connected and disconnected from each other. Alternatively, the sensor **201***b* and the monitor **209***b* can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor **209***b* can be attached to the patient. For example, the monitor **209***b* can include a belt clip or straps (see, e.g., FIG. **2**C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor **209***b* can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable **212** and sensor **201***b* to be attached to the monitor **209**B.

The monitor **209***b* can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor **209***b* can include a display **210***b* that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor **209***b*.

In addition, although a single sensor **201***b* with a single monitor **209***b* is shown, different combinations of sensors and device pairings can be implemented. For example, multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. **2**C illustrates yet another example of monitoring device **200**C that can house the data collection system **100**. Like the monitoring device **200**B, the monitoring device **200**C includes a finger clip sensor **201***c* connected to a monitor **209***c* via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. **2**B. The monitor **209***c* can include all of the features of the monitor

200B described above. For example, the monitor **209***c* includes buttons **208***c* and a display **210***c*. The monitor **209***c* shown also includes straps **214***c* that allow the monitor **209***c* to be attached to a patient's limb or the like.

FIG. **2**D illustrates yet another example of monitoring device **200**D that can house the data collection system **100**. Like the monitoring devices **200**B and **200**C, the monitoring device **200**D includes a finger clip sensor **201***d* connected to a monitor **209***d* via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. **2**B. In addition to having some or all of the features described above with respect to FIGS. **2**B and **2**C, the monitoring device **200**D includes an optional universal serial bus (USB) port **216** and an Ethernet port **218**. The USB port **216** and the Ethernet port **218** can be used, for example, to transfer information between the monitor **209***d* and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor **209***b*, and perform a variety of other functions. The USB port **216** and the Ethernet port **218** can be included with the other monitoring devices **200**A, **200**B, and **200**C described above.

FIGS. **3**A through **3**C illustrate more detailed examples of embodiments of a sensor **301***a*. The sensor **301***a* shown can include all of the features of the sensors **100** and **200** described above.

Referring to FIG. **3**A, the sensor **301***a* in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure **302***a* for receiving a patient's finger. The enclosure **302***a* is formed by an upper section or emitter shell **304***a*, which is pivotably connected with a lower section or detector shell **306***a*. The emitter shell **304***a* can be biased with the detector shell **306***a* to close together around a pivot point **303***a* and thereby sandwich finger tissue between the emitter and detector shells **304***a*, **306***a*.

In an embodiment, the pivot point **303***a* advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells **304***a*, **306***a* to effectively level the sections when applied to a tissue site. In another embodiment, the sensor **301***a* includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell **304***a* can position and house various emitter components of the sensor **301***a*. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metalicized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell **304***a* can also include absorbing opaque material, such as, for example, black or grey colored material, at various areas, such as on one or more flaps **307***a*, to reduce ambient light entering the sensor **301***a*.

The detector shell **306***a* can position and house one or more detector portions of the sensor **301***a*. The detector shell **306***a* can be constructed of reflective material, such as white silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. **1**). The detector shell **306***a* can also include absorbing opaque material at various areas, such as lower area **308***a*, to reduce ambient light entering the sensor **301***a*.

Referring to FIGS. **3**B and **3**C, an example of finger bed **310** is shown in the sensor **301***b*. The finger bed **310** includes a generally curved surface shaped generally to receive

tissue, such as a human digit. The finger bed **310** includes one or more ridges or channels **314**. Each of the ridges **314** has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges **314** can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor **301***a*. The ridges **314** can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds **310**.

Finger bed **310** can also include an embodiment of a tissue thickness adjuster or protrusion **305**. The protrusion **305** includes a measurement site contact area **370** (see FIG. **3**C) that can contact body tissue of a measurement site. The protrusion **305** can be removed from or integrated with the finger bed **310**. Interchangeable, different shaped protrusions **305** can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. **3**C, the contact area **370** of the protrusion **305** can include openings or windows **320**, **321**, **322**, and **323**. When light from a measurement site passes through the windows **320**, **321**, **322**, and **323**, the light can reach one or more photodetectors (see FIG. **3**E). In an embodiment, the windows **320**, **321**, **322**, and **323** mirror specific detector placements layouts such that light can impinge through the protrusion **305** onto the photodetectors. Any number of windows **320**, **321**, **322**, and **323** can be employed in the protrusion **305** to allow light to pass from the measurement site to the photodetectors.

The windows **320**, **321**, **322**, and **323** can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows **320**, **321**, **322**, and **323** can be made from materials, such as plastic or glass. In some embodiments, the windows **320**, **321**, **322**, and **323** can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

Turning to FIG. **3**B, the sensor **301***a* can also include a shielding **315***a*, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding **315***a* is provided in the depicted embodiment below or embedded within the protrusion **305** to reduce noise. The shielding **315***a* can be constructed from a conductive material, such as copper. The shielding **315***a* can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows **320**, **321**, **322**, and **323** on an external surface of the protrusion **305** (see FIG. **3**C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. **3**E).

In some embodiments, the shielding cage for shielding **315***a* can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion **305** (see FIG. **3**E). In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm^2 to about 60 mm^2 was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion **305** can be selected. In making such determinations, consideration can be made of protrusion's **305** effect on blood flow at the measurement site and mean path length for optical radiation passing through openings **320**, **321**, **322**, and **323**. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion **305** can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area **370** to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion **305** can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area **370**. The contact area **370** can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion **305** can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion **305** and the contact area **370** can include a combination of materials with various characteristics.

The contact area **370** serves as a contact surface for the measurement site. For example, in some embodiments, the contact area **370** can be shaped for contact with a patient's finger. Accordingly, the contact area **370** can be sized and shaped for different sizes of fingers. The contact area **370** can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example, the contact area **370** can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. **5** provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

Referring to FIG. **5**, a plot **500** is shown that illustrates examples of effects of embodiments of the protrusion **305** on the SNR at various wavelengths of light. As described above, the protrusion **305** can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion **305** can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I=I_o*e^{-m*b*c}$, where I_o is the initial power of light being transmitted, m is the path

length traveled by the light, and the component "b*c" corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1}. Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $l=l_o*e^{(-20*0.7)}$.

In an embodiment where the protrusion **305** is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box **510**). This results in a new transmittance, $l_1=l_o*e^{(-16.6*0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot **500** of FIG. **5**. The plot **500** illustrates potential effects of the protrusion **305** on the transmittance. As illustrated, comparing l and l_1 results in an intensity gain of $e^{(-16.6*0.7)}/e^{(-20*0.7)}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1}. The plot **500** also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. **3**A through **3**C, an example heat sink **350***a* is also shown. The heat sink **350***a* can be attached to, or protrude from an outer surface of, the sensor **301***a*, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor **301***a* in certain embodiments, the heat sink **350***a* can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. **1**) generate sufficient heat that inclusion of the heat sink **350***a* can advantageously allows the sensor **301***a* to remain safely cooled. The heat sink **350***a* can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell **304***a* can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink **350***a* includes metalicized plastic. The metalicized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink **350***a* can include a thermally conductive liquid crystalline polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, Rhode Island. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink **350***a* provides improved heat transfer properties when the sensor **301***a* is active for short intervals of less than a full day's use. In an embodiment, the heat sink **350***a* can advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink **350***a* can be selected that performs effectively in shorter or longer intervals.

Moreover, the heat sink **350***a* can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink **350***a* is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink **350***a* shown includes fins **351***a* (see FIG. **3**A).

An alternative shape of a sensor **301***b* and heat sink **350***b* is shown in FIG. **3**D. The sensor **301***b* can include some or all of the features of the sensor **301***a*. For example, the sensor **301***b* includes an enclosure **302***b* formed by an emitter shell **304***b* and a detector shell **306***b*, pivotably connected about a pivot **303***a*. The emitter shell **304***b* can also include absorbing opaque material on one or more flaps **307***b*, and the detector shell **306***a* can also include absorbing opaque material at various areas, such as lower area **308***b*.

However, the shape of the sensor **301***b* is different in this embodiment. In particular, the heat sink **350***b* includes comb protrusions **351***b*. The comb protrusions **351***b* are exposed to the air in a similar manner to the fins **351***a* of the heat sink **350***a*, thereby facilitating efficient cooling of the sensor **301***b*.

FIG. **3**E illustrates a more detailed example of a detector shell **306***b* of the sensor **301***b*. The features described with respect to the detector shell **306***b* can also be used with the detector shell **306***a* of the sensor **301***a*.

As shown, the detector shell **306***b* includes detectors **316**. The detectors **316** can have a predetermined spacing **340** from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors **316** and the emitter discussed above.

In the depicted embodiment, the detector shell **316** can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site **102**). In the detector shell **316**, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell **316** can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. **3**E, the detectors **316** can have a spatial configuration of a grid. However, the detectors **316** can be arranged in other configurations that vary the path length. For example, the detectors **316** can be arranged in a linear array, a logarithmic array, a two-dimensional array, a zig-zag pattern, or the like. Furthermore, any number of the detectors **316** can be employed in certain embodiments.

FIG. **3**F illustrates another embodiment of a sensor **301***f*. The sensor **301***f* can include some or all of the features of the sensor **301***a* of FIG. **3**A described above. For example, the sensor **301***f* includes an enclosure **302***f* formed by an upper section or emitter shell **304***f*, which is pivotably connected with a lower section or detector shell **306***f* around a pivot point **303***f*. The emitter shell **304***f* can also include absorbing opaque material on various areas, such as on one or more flaps **307***f*, to reduce ambient light entering the sensor **301***f*. The detector shell **306***f* can also include absorbing opaque material at various areas, such as a lower area **308***f*. The sensor **301***f* also includes a heat sink **350***f*, which includes fins **351***f*.

In addition to these features, the sensor **301***f* includes a flex circuit cover **360**, which can be made of plastic or

another suitable material. The flex circuit cover **360** can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell **304***f* to the detector shell **306***f*. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. **46** and associated description, which is hereby specifically incorporated by reference). The flex circuit cover **360** is shown in more detail below in FIG. **17**.

In addition, sensors **301***a-f* has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. **4**A through **4**C illustrate example arrangements of a protrusion **405**, which is an embodiment of the protrusion **305** described above. In an embodiment, the protrusion **405** can include a measurement site contact area **470**. The measurement site contact area **470** can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion **405** can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion **405** can have a length **400**, a width **410**, and a height **430**. The length **400** can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width **410** can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height **430** can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions **400**, **410**, and **430** can be selected such that the measurement site contact area **470** includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area **470** can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area **470** can be generally curved and/or convex with respect to the measurement site. The measurement site contact area **470** can be other shapes that reduce or even minimize air between the protrusion **405** and/or the measurement site. Additionally, the surface pattern of the measurement site contact area **470** can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. **4**A and **4**C, openings or windows **420**, **421**, **422**, and **423** can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows **420**, **421**, **422**, and **423** can be of non-uniform shapes and sizes. As shown, the windows **420**, **421**, **422**, and **423** can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of arranging the windows **420**, **421**, **422**, and **423** are possible. For example, the windows **420**, **421**, **422**, and **423** can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows **420**, **421**, **422**, and **423** can be placed at different heights with respect to the finger bed **310** of FIG. **3**. The windows **420**, **421**, **422**, and **423** can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

FIGS. **6**A through **6**D illustrate another embodiment of a protrusion **605** that can be used as the tissue shaper **105** described above or in place of the protrusions **305**, **405** described above. The depicted protrusion **605** is a partially cylindrical lens having a partial cylinder **608** and an extension **610**. The partial cylinder **608** can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion **605** focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. **6**A illustrates a perspective view of the partially cylindrical protrusion **605**. FIG. **6**B illustrates a front elevation view of the partially cylindrical protrusion **605**. FIG. **6**C illustrates a side view of the partially cylindrical protrusion **605**. FIG. **6**D illustrates a top view of the partially cylindrical protrusion **605**.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion **605** over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion **605** penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion **605** can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion **605** can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. **14**). If fewer or smaller photodiodes are used, the partially cylindrical protrusion **605** can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion **605** can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. **6**C, the overall height of the partially cylindrical protrusion **605** (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion **605** to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion **605** can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion **605** is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. **6**D, the width of the partially cylindrical protrusion **605** (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration of the partially cylindrical protrusion **605** into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the width of the partially cylindrical protrusion **605** can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion **605** could be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially cylindrical protrusion **605** can be expressed as:

$$f = \frac{R}{n-1},$$

where R is the radius of curvature of the partial cylinder **608** and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion **605** can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion **605** having a material with a higher index of refraction such as nSF11 glass (e.g., n=1.75 at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion **605** can be chosen to improve or optimize the light focusing properties of the protrusion **605**. A plastic partially cylindrical protrusion **605** could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion **605**.

Placing a photodiode at a given distance below the partially cylindrical protrusion **605** can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. **14**). Different sizes of the partially cylindrical protrusion **605** can use different sizes of photodiodes. The extension **610** added onto the bottom of the partial cylinder **608** is used in certain embodiments to increase the height of the partially cylindrical protrusion **605**. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion **605**. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension **610** can also further facilitate the protrusion **605** increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension **610** can be omitted.

FIG. **6**E illustrates another view of the sensor **301***f* of FIG. **3**F, which includes an embodiment of a partially cylindrical protrusion **605***b*. Like the sensor **301**A shown in FIGS. **3**B and **3**C, the sensor **301***f* includes a finger bed **310***f*. The finger bed **310***f* includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed **310***f* also includes the ridges or channels **314** described above with respect to FIGS. **3**B and **3**C.

The example of finger bed **310***f* shown also includes the protrusion **605***b*, which includes the features of the protrusion **605** described above. In addition, the protrusion **605***b* also includes chamfered edges **607** on each end to provide a more comfortable surface for a finger to slide across (see also FIG. **14**D). In another embodiment, the protrusion **605***b* could instead include a single chamfered edge **607** proximal to the ridges **314**. In another embodiment, one or both of the chamfered edges **607** could be rounded.

The protrusion **605***b* also includes a measurement site contact area **670** that can contact body tissue of a measurement site. The protrusion **605***b* can be removed from or integrated with the finger bed **310***f*. Interchangeable, differently shaped protrusions **605***b* can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. **7**A and **7**B illustrate block diagrams of sensors **701** that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors **701** can be implemented with any of the sensors **101**, **201**, **301** described above. Although not shown, the partially cylindrical protrusion **605** of FIG. **6** can also be used with the sensors **701** in certain embodiments.

For example, referring specifically to FIG. **7**A, the sensor **701***a* includes an emitter housing **704***a* and a detector housing **706**. The emitter housing **704***a* includes LEDs **104**. The detector housing **706***a* includes a tissue bed **710***a* with an opening or window **703***a*, the conductive glass **730***a*, and one or more photodiodes for detectors **106** provided on a submount **707***a*.

During operation, a finger **102** can be placed on the tissue bed **710***a* and optical radiation can be emitted from the LEDs **104**. Light can then be attenuated as it passes through or is reflected from the tissue of the finger **102**. The attenuated light can then pass through the opening **703***a* in the tissue bed **710***a*. Based on the received light, the detectors **106** can provide a detector signal **107**, for example, to the front end interface **108** (see FIG. **1**).

In the depicted embodiment, the conductive glass **730** is provided in the opening **703**. The conductive glass **730** can thus not only permit light from the finger to pass to the detectors **106**, but it can also supplement the shielding of the detectors **106** from noise. The conductive glass **730** can include a stack or set of layers. In FIG. **7**A, the conductive glass **730***a* is shown having a glass layer **731** proximate the finger **102** and a conductive layer **733** electrically coupled to the shielding **790***a*.

In an embodiment, the conductive glass **730***a* can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure **790***a*, the conductive glass **730***a* can be electrically coupled to the shielding enclosure **790***a*. The conductive glass **730***a* can be electrically coupled to the shielding **704***a* based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure **790***a* can be provided to encompass the detectors **106** to reduce or prevent noise. For example, the shielding enclosure **790***a* can be constructed from a conductive material, such as copper, in the form of a metal cage. The shielding or enclosure a can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

In some embodiments, the shielding enclosure **790***a* can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790***a* can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

Referring to FIG. **7**B, another block diagram of an example sensor **701***b* is shown. A tissue bed **710***b* of the sensor **701***b* includes a protrusion **705***b*, which is in the form of a convex bump. The protrusion **705***b* can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion **705***b* includes

a contact area **370** that comes in contact with the finger **102** and which can include one or more openings **703***b*. One or more components of conductive glass **730***b* can be provided in the openings **703**. For example, in an embodiment, each of the openings **703** can include a separate window of the conductive glass **730***b*. In an embodiment, a single piece of the conductive glass **730***b* can used for some or all of the openings **703***b*. The conductive glass **730***b* is smaller than the conductive glass **730***a* in this particular embodiment.

A shielding enclosure **790***b* is also provided, which can have all the features of the shielding enclosure **790***a*. The shielding enclosure **790***b* is smaller than the shielding enclosure **790***a*; however, a variety of sizes can be selected for the shielding enclosures **790**.

In some embodiments, the shielding enclosure **790***b* can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790***b* can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

FIGS. **8**A through **8**D illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors **701***a*, **701***b*. As shown in the perspective view of FIG. **8**A and side view of FIG. **8**B, the conductive glass **730** includes the electrically conductive material **733** described above as a coating on the glass layer **731** described above to form a stack. In an embodiment where the electrically conductive material **733** includes indium tin oxide, surface resistivity of the electrically conductive material **733** can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material **733**.

Although the conductive material **733** is shown spread over the surface of the glass layer **731**, the conductive material **733** can be patterned or provided on selected portions of the glass layer **731**. Furthermore, the conductive material **733** can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. **8**C, a side view of a conductive glass **830***a* is shown to illustrate an embodiment where the electrically conductive material **733** is provided as an internal layer between two glass layers **731**, **835**. Various combinations of integrating electrically conductive material **733** with glass are possible. For example, the electrically conductive material **733** can be a layer within a stack of layers. This stack of layers can include one or more layers of glass **731**, **835**, as well as one or more layers of conductive material **733**. The stack can include other layers of materials to achieve desired characteristics.

In FIG. **8**D, a bottom perspective view is shown to illustrate an embodiment where a conductive glass **830***b* can include conductive material **837** that occupies or covers a portion of a glass layer **839**. This embodiment can be useful, for example, to create individual, shielded windows for detectors **106**, such as those shown in FIG. **3**C. The conductive material **837** can be patterned to include an area **838** to allow light to pass to detectors **106** and one or more strips **841** to couple to the shielding **704** of FIG. **7**.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. **9** depicts an example graph **900** that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. **7** and **8**. The graph **900** depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line **915** on the graph **900** illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line **920** on the graph **900** demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line **925** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line **930** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. **10**A through **10**B illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. **10**A, a graph **1000** depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above included separate windows for four (4) detectors **106**. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols **1030-1033** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. **10**B, a graph **1050** depicts a noise floor for frequencies of noise **1070** for an embodiment in which the sensor included separate openings for four (4) detectors **106** and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols **1080-1083** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. **10**A.

FIG. **11**A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter **104** can include a driver **1105**, a thermistor **1120**, a set of top-emitting LEDs **1102** for emitting red and/or infrared light, a set of side-emitting LEDs **1104** for emitting near infrared light, and a submount **1106**.

The thermistor **1120** can be provided to compensate for temperature variations. For example, the thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement cite. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver **1105** can provide pulses of current to the emitter **1104**. In an embodiment, the driver **1105** drives the emitter **1104** in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor **110**). For example, the driver **1105** can drive the emitter **1104** with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver **1105** can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter **1104**. In some embodiments, the driver **1105** is capable of driving the emitter **1104** to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount **1106** provides a support structure in certain embodiments for aligning the top-emitting LEDs **1102** and the side-emitting LEDs **1104** so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount **1106** is also constructed of aluminum nitride (AlN) or beryllium oxide (BEO) for heat dissipation, although other materials or combinations of materials suitable for the submount **1106** can be used.

FIG. **11**B illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter **104** may be driven in a progressive fashion to minimize noise and increase SNR of sensor **101**. For example, emitter **104** may be driven based on a progression of power/current delivered to LEDs **1102** and **1104**.

In some embodiments, emitter **104** may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter **104** may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about

1590 nm to about 1700 nm. Of course, emitter **104** may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. **11**B shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs **1102**. FIG. **11**B also shows that emitter **104** may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs **1104**. Emitter **104** may be progressively driven at higher power/current. This progression may allow driver circuit **105** to stabilize in its operations, and thus, provide a more stable current/power to LEDs **1102** and **1104**.

For example, as shown in FIG. **11**B, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs **1102** may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs **1104** (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit **1105** to stabilize after operating at higher current/power.

As shown in FIG. **11**B, top emitting LEDs **1102** may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs **1102** may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs **502** for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter **104**.

Subsequently, side emitting LEDs **1104** may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site **102** to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment, the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the current needed to drive side emitting LEDs **1104**. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter **104**.

As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit **1105** to stabilize its power delivery to LEDs **1102** and **1104**. Driver circuit **1105** may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to allow for stabilization of driver

circuit **1105**. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system **100**. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit **1105** may monitor temperatures of the LEDs **1102** and **1104** using the thermistor **1120** and adjust the output of LEDs **1102** and **1104** accordingly. Such a temperature may be to help sensor **101** correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. **11**C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter **104** can include components mounted on a substrate **1108** and on submount **1106**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**. Side emitting LEDS **1104** may be mounted on submount **1106**. As noted, side-emitting LEDs **1104** may be included in emitter **104** for emitting near infrared light.

As also shown, the sensor of FIG. **11**C may include a thermistor **1120**. As noted, the thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter **104** may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. **11**D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter **104** that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter **104** can include components mounted on a substrate **1108**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**.

As also shown, the emitter of FIG. **11**D may include a thermistor **1120**. The thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** due to heating.

FIG. **12**A illustrates a detector submount **1200** having photodiode detectors that are arranged in a grid pattern on the detector submount **1200** to capture light at different quadrants from a measurement site. One detector submount **1200** can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount **1200**. The detector submount **1200** can also be used with the partially cylindrical protrusion **605** described above with respect to FIG. **6**.

The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount **1200** to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors **106** and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site **102**). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. **12**B through **12**D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors **106**. As shown, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount **1200** to capture light at different quadrants from measurement site **102**.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors **106** may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors **106** may be employed by embodiments of the present disclosure.

For example, as shown in FIG. **12**B, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount **1200**. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

In FIG. **12**C, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount **1200**, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances D**1**>D**2**>D**3**). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. **12**D, a different substantially grid pattern on submount **1200** of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. **12**E through **12**H illustrate several embodiments of photodiodes that may be used in detectors **106**. As shown in these figures, a photodiode **1202** of detector **106** may comprise a plurality of active areas **1204**. These active areas **204** may be coupled together via a common cathode **1206** or anode **1208** in order to provide a larger effective detection area.

In particular, as shown in FIG. **12**E, photodiode **1202** may comprise two (2) active areas **1204***a* and **1204***b*. In FIG. **12**F, photodiode **1202** may comprise four (4) active areas **1204***c*-*f*. In FIG. **12**G, photodiode **1202** may comprise three (3) active areas **1204***g*-*i*. In FIG. **12**H, photodiode **1202** may comprise nine (9) active areas **1204***j*-*r*. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher

purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode **1202**.

FIG. **13** illustrates an example multi-stream process **1300**. The multi-stream process **1300** can be implemented by the data collection system **100** and/or by any of the sensors described above. As shown, a control signal from a signal processor **1310** controls a driver **1305**. In response, an emitter **1304** generates a pulse sequence **1303** from its emitter (e.g., its LEDs) into a measurement site or sites **1302**. As described above, in some embodiments, the pulse sequence **1303** is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence **1303** can be greater (or smaller).

In response to the pulse sequence **1300**, detectors 1 to n (n being an integer) in a detector **1306** capture optical radiation from the measurement site **1302** and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter **1304**. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface **1308** can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor **1310**. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter **1304**.

The signal processor **1310** can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor **1310** can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

Absorbance A=m*b*c, where:

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of M^{-1} cm^{-1});

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$$T=l/l_o, \text{ where:}$$

l is the light intensity measured by the instrument from the measurement site; and

l_o is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A=-\log T$$

Therefore, substituting equations from above:

$$A=-\log(l/l_o)$$

In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(l/l_o)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (l_o), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude that what is achievable by currently available technology.

In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T=e^{-m*b*c}$$

In terms of light intensity, this equation can also be rewritten as:

$$l/l_o=e^{-m*b*c}$$

Or, at a detector, the measured light (l) can be expressed as:

$$l=l_o*e^{-m*b*c}$$

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $l_1 \ldots l_n$ streams of measurements. Assuming each of these detectors have their

own path lengths, $b_1 \ldots b_n$, from the light source, the measured light intensities can be expressed as:

$$l_n = l_o * e^{-m*b_n*c}$$

The measured light intensities at any two different detectors can be referenced to each other. For example:

$$l_1/l_n = (l_o * e^{-mb_1c})/(l_o * e^{-mb_nc})$$

As can be seen, the terms, l_o, cancel out and, based on exponent algebra, the equation can be rewritten as:

$$l_1/l_n = e^{-m(o_1-b_n)c}$$

From this equation, the analyte concentration (c) can now be derived from bulk signals $l_1 \ldots l_n$ and knowing the respective mean path lengths b_1 and b_n. This scheme also allows for the cancelling out of l_o, and thus, noise generated by the emitter **1304** can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) **1302**. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. **14**A illustrates an embodiment of a detector submount **1400***a* positioned beneath the partially cylindrical protrusion **605** of FIG. **6** (or alternatively, the protrusion **605***b*). The detector submount **1400***a* includes two rows **1408***a* of detectors **1410***a*. The partially cylindrical protrusion **605** can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion **605** can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion **605**, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

Applying the partially cylindrical protrusion **605** to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion **605** (see FIG. **14**B). This is the example situation illustrated in FIG. **14**—two rows **1408***a* of detectors **1410***a* are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion **605** can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. **14**B depicts a front elevation view of the partially cylindrical protrusion **605** (or alternatively, the protrusion **605***b*) that illustrates how light from emitters (not shown) can be focused by the protrusion **605** onto detectors. The protrusion **605** is placed above a detector submount **1400***b* having one or more detectors **1410***b* disposed thereon. The submount **1400***b* can include any number of rows of detectors **1410**, although one row is shown.

Light, represented by rays **1420**, is emitted from the emitters onto the protrusion **605**. These light rays **1420** can be attenuated by body tissue (not shown). When the light rays **1420** enter the protrusion **605**, the protrusion **605** acts as a lens to refract the rays into rays **1422**. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion **605**. The refraction causes the rays **1422** to be focused or substantially focused on the one or more detectors **1410***b*. Since the light is focused on a smaller area, a sensor including the protrusion **605** can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. **14**C illustrates another embodiment of a detector submount **1400***c*, which can be disposed under the protrusion **605***b* (or alternatively, the protrusion **605**). The detector submount **1400***c* includes a single row **1408***c* of detectors **1410***c*. The detectors are electrically connected to conductors **1412***c*, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount **1400***c* is shown positioned under the protrusion **605***b* in a detector subassembly **1450** illustrated in FIG. **14**D. A top-down view of the detector subassembly **1450** is also shown in FIG. **14**E. In the detector subassembly **1450**, a cylindrical housing **1430** is disposed on the submount **1400***c*. The cylindrical housing **1430** includes a transparent cover **1432**, upon which the protrusion **605***b* is disposed. Thus, as shown in FIG. **14**D, a gap **1434** exists between the detectors **1410***c* and the protrusion **605***b*. The height of this gap **1434** can be chosen to increase or maximize the amount of light that impinges on the detectors **1410***c*.

The cylindrical housing **1430** can be made of metal, plastic, or another suitable material. The transparent cover **1432** can be fabricated from glass or plastic, among other materials. The cylindrical housing **1430** can be attached to the submount **1400***c* at the same time or substantially the same time as the detectors **1410***c* to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing **1430** in various embodiments.

In certain embodiments, the cylindrical housing **1430** (and transparent cover **1432**) forms an airtight or substantially airtight or hermetic seal with the submount **1400***c*. As a result, the cylindrical housing **1430** can protect the detectors **1410***c* and conductors **1412***c* from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing **1430** can protect the detectors **1410***c* and conductors **1412***c* more effectively than currently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing **1430** is at least partially made of metal, the cylindrical housing **1430** can provide noise shielding for the detectors **1410***c*. For example, the cylindrical housing **1430** can be soldered to a ground connection or ground plane on the submount **1400***c*, which allows the cylindrical housing **1430** to reduce noise. In another embodiment, the transparent cover **1432** can include a conductive material or conductive layer, such as

conductive glass or plastic. The transparent cover **1432** can include any of the features of the noise shields **790** described above.

The protrusion **605***b* includes the chamfered edges **607** described above with respect to FIG. **6**E. These chamfered edges **607** can allow a patient to more comfortably slide a finger over the protrusion **605***b* when inserting the finger into the sensor **301***f*.

FIG. **14**F illustrates a portion of the detector shell **306***f*, which includes the detectors **1410***c* on the substrate **1400***c*. The substrate **1400***c* is enclosed by a shielding enclosure **1490**, which can include the features of the shielding enclosures **790***a*, **790***b* described above (see also FIG. **17**). The shielding enclosure **1490** can be made of metal. The shielding enclosure **1490** includes a window **1492***a* above the detectors **1410***c*, which allows light to be transmitted onto the detectors **1410***c*.

A noise shield **1403** is disposed above the shielding enclosure **1490**. The noise shield **1403**, in the depicted embodiment, includes a window **1492***a* corresponding to the window **1492***a*. Each of the windows **1492***a*, **1492***b* can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows **1492***a*, **1492***b* may be selected to have different sizes or shapes from each other.

The noise shield **1403** can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield **1403** extends about three-quarters of the length of the detector shell **306***f*. In other embodiments, the noise shield **1403** could be smaller or larger. The noise shield **1403** could, for instance, merely cover the detectors **1410***c*, the submount **1400***c*, or a portion thereof. The noise shield **1403** also includes a stop **1413** for positioning a measurement site within the sensor **301***f*. Advantageously, in certain embodiments, the noise shield **1403** can reduce noise caused by light piping.

A thermistor **1470** is also shown. The thermistor **1470** is attached to the submount **1400***c* and protrudes above the noise shield **1403**. As described above, the thermistor **1470** can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors **1410***c* are not enclosed in the cylindrical housing **1430**. In an alternative embodiment, the cylindrical housing **1430** encloses the detectors **1410***c* and is disposed under the noise shield **1403**. In another embodiment, the cylindrical housing **1430** encloses the detectors **1410***c* and the noise shield **1403** is not used. If both the cylindrical housing **1403** and the noise shield **1403** are used, either or both can have noise shielding features.

FIG. **14**G illustrates the detector shell **306***f* of FIG. **14**F, with the finger bed **310***f* disposed thereon. FIG. **14**H illustrates the detector shell **306***f* of FIG. **14**G, with the protrusion **605***b* disposed in the finger bed **310***f*.

FIG. **14**I illustrates a cutaway view of the sensor **301***f*. Not all features of the sensor **301***f* are shown, such as the protrusion **605***b*. Features shown include the emitter and detector shells **304***f*, **306***f*, the flaps **307***f*, the heat sink **350***f* and fins **351***f*, the finger bed **310***f*, and the noise shield **1403**.

In addition to these features, emitters **1404** are depicted in the emitter shell **304***f*. The emitters **1404** are disposed on a submount **1401**, which is connected to a circuit board **1419**. The emitters **1404** are also enclosed within a cylindrical

housing **1480**. The cylindrical housing **1480** can include all of the features of the cylindrical housing **1430** described above. For example, the cylindrical housing **1480** can be made of metal, can be connected to a ground plane of the submount **1401** to provide noise shielding, and can include a transparent cover **1482**.

The cylindrical housing **1480** can also protect the emitters **1404** from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing **1480** can provide a gap between the emitters **1404** and the measurement site (not shown), which can allow light from the emitters **1404** to even out or average out before reaching the measurement site.

The heat sink **350***f*, in addition to including the fins **351***f*, includes a protuberance **352***f* that extends down from the fins **351***f* and contacts the submount **1401**. The protuberance **352***f* can be connected to the submount **1401**, for example, with thermal paste or the like. The protuberance **352***f* can sink heat from the emitters **1404** and dissipate the heat via the fins **351***f*.

FIGS. **15**A and **15**B illustrate embodiments of sensor portions **1500**A, **1500**B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions **1500**A, **1500**B shown include LED emitters **1504**; however, for ease of illustration, the detectors have been omitted. The sensor portions **1500**A, **1500**B shown can be included, for example, in any of the emitter shells described above.

The LEDs **1504** of the sensor portions **1500**A, **1500**B are connected to a substrate or submount **1502**. The submount **1502** can be used in place of any of the submounts described above. The submount **1502** can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable **1512** is attached to the submount **1502** and includes electrical wiring **1514**, such as twisted wires and the like, for communicating with the LEDs **1504**. The cable **1512** can correspond to the cables **212** described above.

Although not shown, the cable **1512** can also include electrical connections to a detector. Only a portion of the cable **1512** is shown for clarity. The depicted embodiment of the cable **1512** includes an outer jacket **1510** and a conductive shield **1506** disposed within the outer jacket **1510**. The conductive shield **1506** can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield **1506** or a portion of the conductive shield **1506** can be electrically connected to the submount **1502** and can reduce noise in the signal generated by the sensor **1500**A, **1500**B by reducing RF coupling with the wires **1514**. In alternative embodiments, the cable **1512** does not have a conductive shield. For example, the cable **1512** could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. **15**A, in certain embodiments, the conductive shield **1506** can act as a heat sink for the LEDs **1504** by absorbing thermal energy from the LEDs **1504** and/or the submount **1502**. An optional heat insulator **1520** in communication with the submount **1502** can also assist with directing heat toward the conductive shield **1506**. The heat insulator **1520** can be made of plastic or another suitable material. Advantageously, using the conductive shield **1506** in the cable **1512** as a heat sink can, in certain embodiments, reduce cost for the sensor.

Referring to FIG. **15**B, the conductive shield **1506** can be attached to both the submount **1502** and to a heat sink layer **1530** sandwiched between the submount **1502** and the optional insulator **1520**. Together, the heat sink layer **1530** and the conductive shield **1506** in the cable **1512** can absorb at least part of the thermal energy from the LEDs and/or the submount **1502**.

FIGS. **15**C and **15**D illustrate implementations of a sensor portion **1500**C that includes the heat sink features of the sensor portion **1500**A described above with respect to FIG. **15**A. The sensor portion **1500**C includes the features of the sensor portion **1500**A, except that the optional insulator **1520** is not shown. FIG. **15**D is a side cutaway view of the sensor portion **1500**C that shows the emitters **1504**.

The cable **1512** includes the outer jacket **1510** and the conductive shield **1506**. The conductive shield **1506** is soldered to the submount **1502**, and the solder joint **1561** is shown. In some embodiments, a larger solder joint **1561** can assist with removing heat more rapidly from the emitters **1504**. Various connections **1563** between the submount **1502** and a circuit board **1519** are shown. In addition, a cylindrical housing **1580**, corresponding to the cylindrical housing **1480** of FIG. **14**I, is shown protruding through the circuit board **1519**. The emitters **1504** are enclosed in the cylindrical housing **1580**.

FIGS. **15**E and **15**F illustrate implementations of a sensor portion **1500**E that includes the heat sink features of the sensor portion **1500**B described above with respect to FIG. **15**B. The sensor portion **1500**E includes the heat sink layer **1530**. The heat sink layer **1530** can be a metal plate, such as a copper plate or the like. The optional insulator **1520** is not shown. FIG. **15**F is a side cutaway view of the sensor portion **1500**E that shows the emitters **1504**.

In the depicted embodiment, the conductive shield **1506** of the cable **1512** is soldered to the heat sink layer **1530** instead of the submount **1502**. The solder joint **1565** is shown. In some embodiments, a larger solder joint **1565** can assist with removing heat more rapidly from the emitters **1504**. Various connections **1563** between the submount **1502** and a circuit board **1519** are shown. In addition, the cylindrical housing **1580** is shown protruding through the circuit board **1519**. The emitters **1504** are enclosed in the cylindrical housing **1580**.

FIGS. **15**G and **15**H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. **1** through **15**F. Referring to FIG. **15**G, the circuit board **1519** includes a female connector **1575** that mates with a male connector **1577** connected to a daughter board **1587**. The daughter board **1587** includes connections to the electrical wiring **1514** of the cable **1512**. The connected boards **1519**, **1587** are shown in FIG. **15**H. Also shown is a hole **1573** that can receive the cylindrical housing **1580** described above.

Advantageously, in certain embodiments, using a daughter board **1587** to connect to the circuit board **1519** can enable connections to be made more easily to the circuit board **1519**. In addition, using separate boards can be easier to manufacture than a single circuit board **1519** with all connections soldered to the circuit board **1519**.

FIG. **15**I illustrates an exemplary architecture for front-end interface **108** as a transimpedance-based front-end. As noted, front-end interfaces **108** provide an interface that adapts the output of detectors **106** into a form that can be handled by signal processor **110**. As shown in this figure, sensor **101** and front-end interfaces **108** may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor **101** and front end interfaces **108** may comprise multiple components or circuits that are coupled together.

Front-end interfaces **108** may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors **106**. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter **900** may be integrated with the transimpedance-based front-end in sensor **101**.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector **106**, the applicants developed a noise model to assist in configuring front-end **108**. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise}=\sqrt{aR+bR^2},\text{ where:}$$

aR is characteristic of the impedance of the transimpedance amplifier; and

bR^2 is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector **106**.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in FIG. **12**A) may each comprise four photodiodes. In some embodiments, each detector of four photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. **15**J.

Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the

transimpedance amplifiers in this setting may also be set according to the model shown in FIG. **15**J.

As yet another alternative, as noted above with respect to FIGS. **12**E through **12**H, the photodiodes in detectors **106** may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. **15**J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary "4 PD per stream" sensor **1502** is shown where detector **106** comprises four photodiodes **1502**. The photodiodes **1502** are coupled to a single transimpedance amplifier **1504** to produce an output stream **1506**. In this example, the transimpedance amplifier comprises 10 MΩ resistors **1508** and **1510**. Thus, output stream **1506** is produced from the four photodiodes (PD) **1502**. As shown in the graph of FIG. **15**J, the model indicates that resistance values of about 10 MΩ may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary "1 PD per stream" sensor **1512** is also shown in FIG. **15**J. In particular, sensor **1512** may comprise a plurality of detectors **106** that each comprises a single photodiode **1514**. In addition, as shown for this example configuration, each of photodiodes **1514** may be coupled to respective transimpedance amplifiers **1516**, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 MΩ resistors **1518**. As also shown in the graph of FIG. **15**J, the model illustrates that resistance values of 40 MΩ for resistors **1518** may serve as an alternative to the 4 photodiode per stream architecture of sensor **1502** described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor **1512** may provide enhanced performance because each of transimpedance amplifiers **1516** can be tuned or optimized to its respective photodiodes **1518**. In some embodiments, an averaging component **1520** may also be used to help cancel or reduce noise across photodiodes **1518**.

For purposes of illustration, FIG. **15**K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor **1522** may comprise a "4 PD per stream" architecture on a submount **700** in which each detector **106** comprises four (4) photodiodes **1524**. As shown for sensor **1522**, the output of each set of four photodiodes **1524** is then aggregated into a single transimpedance amplifier **1526** to produce a signal.

As another example, a sensor **1528** may comprise a "1 PD per stream" architecture on submount **700** in which each detector **106** comprises four (4) photodiodes **1530**. In sensor **1528**, each individual photodiode **1530** is coupled to a respective transimpedance amplifier **1532**. The output of the amplifiers **1532** may then be aggregated into averaging circuit **1520** to produce a signal.

As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor **1534** illustrates an exemplary "4 PD per stream" sensor in which the detectors **106** comprise photodiodes **1536** arranged in a linear fashion. Likewise, sensor **1538** illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes **1540** arranged in a linear fashion.

Alternatively, sensor **1542** illustrates an exemplary "4 PD per stream" sensor in which the detectors **106** comprise photodiodes **1544** arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor **1546** illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes **1548** also arranged in a zig-zag pattern.

FIG. **15**L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces **108** may be implemented using switched capacitor circuits and any number of front-end interfaces **108** may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface **1000** and signal processor **110**. Switched capacitor circuits may be useful in system **100** for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces **108** may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces **108** may require less computational power by signal processor **110** to perform the same amount of decimation to obtain the same SNR.

FIGS. **16**A and **16**B illustrate embodiments of disposable optical sensors **1600**. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors **1600** shown. For instance, the sensors **1600** can be used as the sensors **101** in the system **100** described above with respect to FIG. **1**. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors **1600** include an adult/pediatric sensor **1610** for finger placement and a disposable infant/neonate sensor **1602** configured for toe, foot or hand placement. Each sensor **1600** has a tape end **1610** and an opposite connector end **1620** electrically and mechanically interconnected via a flexible coupling **1630**. The tape end **1610** attaches an emitter and detector to a tissue site. Although not shown, the tape end **1610** can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

The sensor signal is communicated via the flexible coupling **1630** to the connector end **1620**. The connector end **1620** can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. **2**A through **2**D. Alternatively, the connector end **1620** can mate directly with the monitor.

FIG. **17** illustrates an exploded view of certain of the components of the sensor ***301f*** described above. A heat sink **1751** and a cable **1781** attach to an emitter shell **1704**. The emitter shell attaches to a flap housing **1707**. The flap housing **1707** includes a receptacle **1709** to receive a cylin-

drical housing **1480/1580** (not shown) attached to an emitter submount **1702**, which is attached to a circuit board **1719**.

A spring **1787** attaches to a detector shell **1706** via pins **1783**, **1785**, which hold the emitter and detector shells **1704**, **1706** together. A support structure **1791** attaches to the detector shell **1706**, which provides support for a shielding enclosure **1790**. A noise shield **1713** attaches to the shielding enclosure **1790**. A detector submount **1700** is disposed inside the shielding enclosure **1790**. A finger bed **1710** provides a surface for placement of the patient's finger. Finger bed **1710** may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion **1705** may also be disposed in the finger bed **1710**. As shown, finger bed **1710** attaches to the noise shield **1703**. The noise shield **1703** may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield **1703** may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield **1703** may also comprise a thermistor **1712**. The thermistor **1712** may be helpful in measuring the temperature of a patient's finger. For example, the thermistor **1712** may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor **1712** may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover **1706** attaches to the pins **1783**, **1785**. Although not shown, a flex circuit can also be provided that connects the circuit board **1719** with the submount **1700** (or a circuit board to which the submount **1700** is connected). A flex circuit protector **1760** may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector **1760** may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector **1760** may be constructed from well known materials, such as a plastic or rubber materials.

FIG. **18** shows the results obtained by an exemplary sensor **101** of the present disclosure that was configured for measuring glucose. This sensor **101** was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor **101** were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

FIG. **19** shows the results obtained by an exemplary sensor **101** of the present disclosure that was configured for measuring glucose. This sensor **101** was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor **101** were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

FIGS. **20** through **22** shows other results that can be obtained by an embodiment of system **100**. In FIG. **20**, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with an embodiment of system **100** that comprised four LEDs and four independent detector streams. As shown, the system **100** obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. **21**, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system **100** that comprised four LEDs in emitter **104** and four independent detector streams from detectors **106**. As shown, the system **100** was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. **22** relate to total hemoglobin testing with an exemplary sensor **101** of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system **100** that comprised four LEDs in emitter **104** and four independent detector channels from detectors **106**. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

What is claimed is:

1. A noninvasive optical physiological sensor comprising:

a plurality of emitters configured to emit light into tissue of a user;

a plurality of detectors configured to detect light that has been attenuated by tissue of the user, wherein the plurality of detectors comprise at least four detectors;

a housing configured to house at least the plurality of detectors in a circular portion of the housing; and

a lens configured to be located between tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is worn by the user, wherein the lens comprises a single outwardly protruding convex surface configured to cause tissue of the user to conform to at least a portion of the single outwardly protruding convex surface when the noninvasive optical physiological sensor is worn by the user and during operation of the noninvasive optical physiological sensor.

2. The noninvasive optical physiological sensor of claim **1**, wherein the plurality of detectors are arranged on a two-dimensional surface of the housing.

3. The noninvasive optical physiological sensor of claim **2**, wherein a first detector and a second detector of the plurality of detectors are arranged across from each other on opposite sides of a central point along a first axis, and a third detector and a fourth detector of the plurality of detectors are arranged across from each other on opposite sides of the central point along a second axis which is perpendicular to the first axis.

4. The noninvasive optical physiological sensor of claim **3**, wherein the lens is comprised of a rigid material.

5. The noninvasive optical physiological sensor of claim **4**, wherein the at least four detectors are evenly spaced from one another.

6. The noninvasive optical physiological sensor of claim **4**, wherein the lens is configured to reduce a mean path length of light traveling to the plurality of detectors.

7. The noninvasive optical physiological sensor of claim **4**, wherein the lens is configured to increase a signal to noise ratio of the noninvasive optical physiological sensor.

8. The noninvasive optical physiological sensor of claim **4**, wherein the lens is configured to increase a signal strength per area of the plurality of detectors.

9. An optical physiological measurement sensor comprising:

a plurality of emitters configured to emit light into tissue of a user;

a housing including a planar surface;

at least four detectors arranged on the planar surface of the housing, wherein the four detectors are arranged in a grid pattern; and

a lens forming a cover of the housing, wherein at least a portion of the lens protrudes from the housing and the lens comprises a single convex surface.

10. The optical physiological measurement sensor of claim **9**, wherein the lens is configured to cause tissue of the user to conform to at least a portion of the single convex surface when the optical physiological measurement sensor is worn by the user.

11. The optical physiological measurement sensor of claim **10**, wherein the four detectors are arranged in a grid pattern such that a first detector and a second detector are arranged across from each other on opposite sides of a central point along a first axis, and a third detector and a fourth detector are arranged across from each other on opposite sides of the central point along a second axis which is perpendicular to the first axis.

12. The optical physiological measurement sensor of claim **11**, wherein the lens is comprised of a rigid material.

13. The optical physiological measurement sensor of claim **12**, wherein the lens is configured to be positioned between the at least four detectors and tissue of a user when the optical physiological measurement sensor is worn by the user.

14. The optical physiological measurement sensor of claim **13**, wherein the lens is configured to press against and at least partially deform tissue of the user when the optical physiological measurement sensor is worn by the user.

15. The optical physiological measurement sensor of claim **14**, wherein the at least four detectors are evenly spaced from one another.

16. The optical physiological measurement sensor of claim **15**, wherein the lens is configured to reduce a mean path length of light traveling to the at least four detectors.

17. The optical physiological measurement sensor of claim **15**, wherein the lens is configured to increase a signal to noise ratio of the optical physiological measurement sensor.

18. The optical physiological measurement sensor of claim **15**, wherein the lens is configured to increase a signal strength per area of the at least four detectors.

19. The optical physiological measurement sensor of claim **9**, wherein the lens comprises a light concentration window.

* * * * *

Case: 22-2069 Document: 26-3 Page: 105 Filed: 09/16/2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,
Patent Owner/Appellant

Appeal Nos. 2022-2069[1]
2022-2070
2022-2071
2022-2072

v.

APPLE INC.,
Petitioner/Appellee

Proceeding Nos.: IPR2021-00193, IPR2021-00195, IPR2021-00208 and IPR2021-00209

NOTICE FORWARDING CERTIFIED LIST

A Notice of Appeal to the United States Court of Appeals for the Federal Circuit was timely filed July 27, 2022, in the United States Patent and Trademark Office in connection with the above identified *Inter Partes Review* proceedings. Pursuant to 35 U.S.C. § 143, a Certified List is this day being forwarded to the Federal Circuit.

Respectfully submitted,

Date: September 1, 2022

By: Macia L. Fletcher
Macia L. Fletcher
Paralegal
Mail Stop 8
P.O. Box 1450
Alexandria, VA 22313-1450
571-272-9035

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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[1] Appeal No. 2022-2069 (Lead) is consolidated with Appeal Nos. 2022-2070, 2022-2071 and 2022-2072 (Members) pursuant to Court Order (Dkt. 2) and Note to File (Dkt. 3) dated August 5, 2022.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing NOTICE FORWARDING CERTIFIED LIST has been served, via electronic mail, on counsel for Appellant and Appellee this 1st day of September, 2022, as follows:

PATENT OWNER:	PETITIONER:
Joseph R. Re Jeremiah Helm Stephen C. Jensen Jarom D. Kesler Stephen W. Larson KNOBBE, MARTENS, OLSON & BEAR, LLP joseph.re@knobbe.com jeremiah.helm@knobbe.com steve.jensen@knobbe.com jarom.kesler@knobbe.com stephen.larson@knobbe.com	Lauren Ann Degnan Ashley Bolt Christopher Dryer Walter Karl Renner Adi Williams FISH & RICHARDSON PC degnan@fr.com bolt@fr.com dryer@fr.com renner@fr.com awilliams@fr.com

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U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

September 1, 2022
(Date)

THIS IS TO CERTIFY that the attached document is a list of the papers that comprise the record before the Patent Trial and Appeal Board (PTAB) for the *Inter Partes Review* proceeding identified below.

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case: IPR2021-00193
Patent No. 10,299,708 B1
By authority of the

DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer

Prosecution History ~ IPR2021-00193

Date	Document
11/20/2020	Petition for Inter Partes Review
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U.S. DEPARTMENT OF COMMERCE
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(Date)

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APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case: IPR2021-00195
Patent No. 10,376,190 B1

By authority of the

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer

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APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case: IPR2021-00208
Patent No. 10,258,266 B1

By authority of the

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer

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U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

September 1, 2022
(Date)

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APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case: IPR2021-00209
Patent No. 10,376,191 B1

By authority of the

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer

Prosecution History ~ IPR2021-00209

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5/25/2022	Final Written Decision

Trials@uspto.gov
571-272-7822

Paper 30
Date: June 1, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2021-00193
Patent 10,299,708 B1

Before JOSIAH C. COCKS, ROBERT L. KINDER, and AMANDA F. WIEKER, *Administrative Patent Judges.*

KINDER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

Apple Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 1–29 ("challenged claims") of U.S. Patent No. 10,299,708 B1 (Ex. 1001, "the '708 patent"). We instituted the petitioned review (Paper 7, "Institution Decision" or "Inst. Dec.").

Masimo Corporation ("Patent Owner") filed a Patent Owner Response (Paper 14, "PO Resp.") to oppose the Petition. Petitioner filed a Reply (Paper 16, "Pet. Reply") to the Patent Owner Response. Patent Owner filed a Sur-reply (Paper 19, "Sur-reply") to the Reply. We conducted an oral hearing on March 15, 2022. A transcript has been entered into the record (Paper 29, "Tr.").

We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a). This Decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of claims 1–29 of the '708 patent. We determine Petitioner has shown by a preponderance of the evidence that those claims are unpatentable.

B. Related Matters

The parties identify the following matters related to the '708 patent:

Masimo Corporation v. Apple Inc., Civil Action No. 8:20-cv-00048 (C.D. Cal.) (filed Jan. 9, 2020);

Apple Inc. v. Masimo Corporation, IPR2020-01520 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,258,265 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01521 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,292,628 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01523 (PTAB Sept. 9, 2020) (challenging claims of U.S. Patent No. 8,457,703 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01524 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,433,776 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01526 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 6,771,994 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01536 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01537 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01538 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01539 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01713 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,624,564 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01714 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01715 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01716 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,702,194 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01722 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01723 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01733 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,702,195 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01737 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,709,366 B1)

Apple Inc. v. Masimo Corporation, IPR2021-00195 (PTAB Nov. 20, 2020) (challenging claims of U.S. Patent No. 10,376,190 B1);

Apple Inc. v. Masimo Corporation, IPR2021-00208 (PTAB Nov. 20, 2020) (challenging claims of U.S. Patent No. 10,258,266 B1); and

Apple Inc. v. Masimo Corporation, IPR2021-00209 (PTAB Nov. 20, 2020) (challenging claims of U.S. Patent No. 10,376,191 B1).

Pet. 97–98; Paper 3, 3–4.

Patent Owner further identifies the following pending patent applications, among other issued and abandoned applications, that claim priority to, or share a priority claim with, the ’708 patent:

U.S. Patent Application No. 16/834,538;

U.S. Patent Application No. 17/031,407;

U.S. Patent Application No. 17/031,316;

U.S. Patent Application No. 17/031,356;

U.S. Patent Application No. 16/449,143; and

U.S. Patent Application No. 16/805,605.

Paper 3, 2–3.

C. The ’708 Patent

The ’708 patent is titled “Multi-Stream Data Collection System for Noninvasive Measurement of Blood Constituents,” and issued on May 28, 2019, from U.S. Patent Application No. 16/261,366, filed Jan. 29, 2019. Ex. 1001, codes (21), (22), (45), (54). The ’708 patent claims priority

through a series of continuation and continuation-in-part applications to Provisional Application Nos. 61/078,228 and 61/078,207, both filed July 3, 2008. *Id.* at codes (60), (63).

The ’708 patent discloses a two-part data collection system including a noninvasive sensor that communicates with a patient monitor. *Id.* at 2:31–33. The sensor includes a sensor housing, an optical source, and several photodetectors, and is used to measure a blood constituent or analyte, e.g., oxygen or glucose. *Id.* at 2:22–28, 2:57–58. The patient monitor includes a display and a network interface for communicating with a handheld computing device. *Id.* at 2:38–40.

Figure 1 of the ’708 patent is reproduced below.

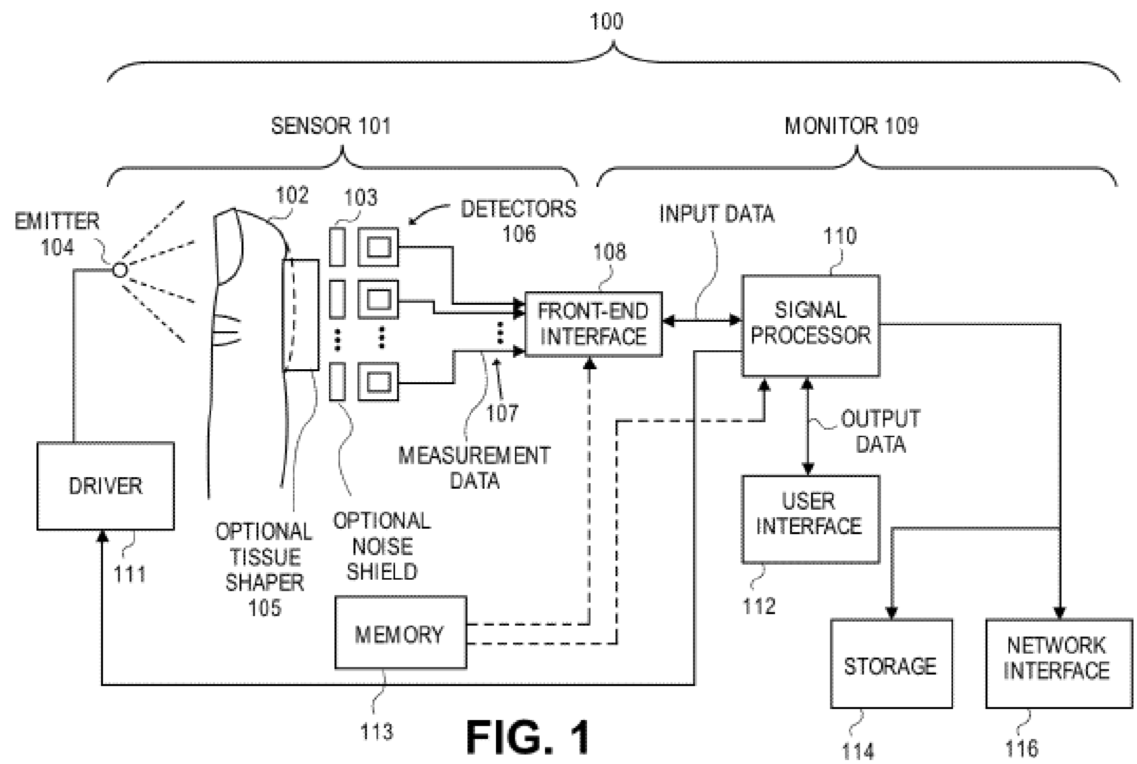

FIG. 1

Figure 1 illustrates a block diagram of data collection system 100 including sensor 101 and monitor 109. *Id.* at 11:36–47. Sensor 101 includes optical emitter 104 and detectors 106. *Id.* at 11:48–52. Emitters 104 emit light that

is attenuated or reflected by the patient's tissue at measurement site 102. *Id.* at 13:60–67. Detectors 106 capture and measure the light attenuated or reflected from the tissue. *Id.* In response to the measured light, detectors 106 output detector signals 107 to monitor 109 through front-end interface 108. *Id.* at 13:64–66, 14:16–22. Sensor 101 also may include tissue shaper 105, which may be in the form of a convex surface that: (1) reduces the thickness of the patient's measurement site; and (2) provides more surface area from which light can be detected. *Id.* at 10:61–11:3.

Monitor 109 includes signal processor 110 and user interface 112. *Id.* at 15:6–8. "[S]ignal processor 110 includes processing logic that determines measurements for desired analytes . . . based on the signals received from the detectors." *Id.* at 15:10–14. User interface 112 presents the measurements to a user on a display, e.g., a touch-screen display. *Id.* at 15:38–48. The monitor may be connected to storage device 114 and network interface 116. *Id.* at 15:52–16:3.

The '708 patent describes various examples of sensor devices. Figures 14D and 14F, reproduced below, illustrate sensor devices.

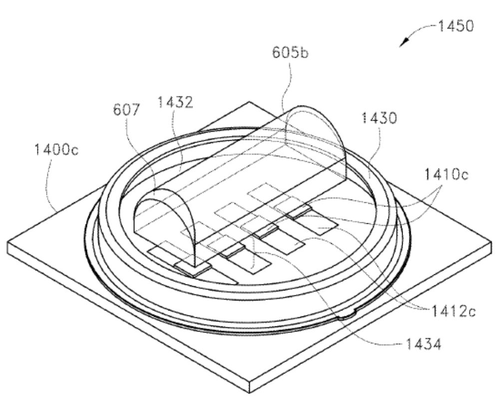

FIG. 14D

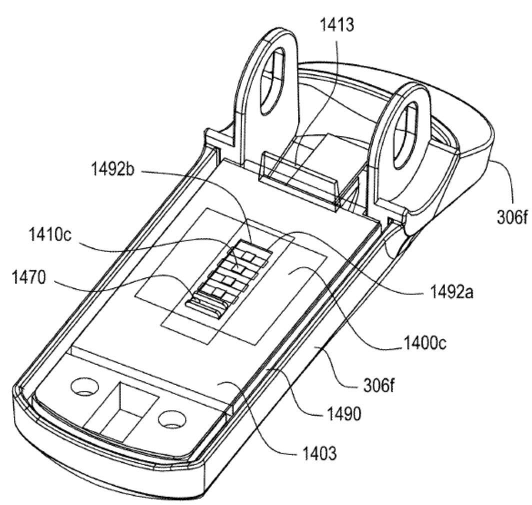

FIG. 14F

Figure 14D illustrates portions of a detector submount and Figure 14F illustrates portions of a detector shell. *Id.* at 6:34–37. As shown in Figure 14D, multiple detectors 1410c are located within housing 1430 and under transparent cover 1432, on which protrusion 605b (or partially cylindrical protrusion 605) is disposed. *Id.* at 35:23–25, 36:17–24. Figure 14F illustrates a detector shell 306f including detectors 1410c on substrate 1400c. *Id.* at 36:63–37:4. Substrate 1400c is enclosed by shielding enclosure 1490 and noise shield 1403, which include window 1492a and window 1492b, respectively, placed above detectors 1410c. *Id.* Alternatively, cylindrical housing 1430 may be disposed under noise shield 1403 and may enclose detectors 1410c. *Id.* at 37:34–36.

Figures 4A and 4B, reproduced below, illustrate an alternative example of a tissue contact area of a sensor device.

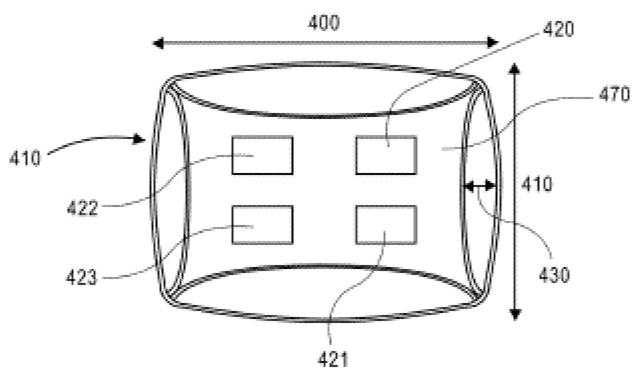

FIG. 4A

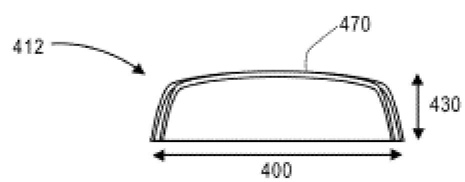

FIG. 4B

Figures 4A and 4B illustrate arrangements of protrusion 405 including measurement contact area 470. *Id.* at 23:8–14. "[M]easurement site contact area 470 can include a surface that molds body tissue of a measurement site." *Id.* "For example, . . . measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site." *Id.* at 23:31–33. The measurement site contact area may include windows 420–

423 that "mimic or approximately mimic a configuration of, or even house, a plurality of detectors." *Id.* at 23:39–53.

D. Illustrative Claim

Of the challenged claims, claims 1 and 19 are independent. Claim 1 is illustrative and is reproduced below.

> 1. A noninvasive optical physiological sensing system comprising:
>
> [a] a platform including a planar surface;
>
> [b] a housing including a raised edge portion extending from and enclosing at least a portion of the planar surface;
>
> [c] at least four detectors arranged on the planar surface of the platform and within the housing, wherein the at least four detectors are arranged in a grid pattern such that a first detector and a second detector are arranged across from each other on opposite sides of a central point along a first axis, and a third detector and a fourth detector are arranged across from each other on opposite sides of the central point along a second axis which is perpendicular to the first axis; and
>
> [d] the housing including a protruding light permeable cover.

Ex. 1001, 44:36–50 (bracketed identifiers [a]–[d] added). Independent claim 19 includes limitations similar to limitations [a]–[d] of claim 1 but also requires distinct limitations discussed more below. *Id.* at 45:53–46:11 (reciting a "platform," "at least four detectors," and a "light permeable cover . . . protruding above the raised wall").

E. Evidence Relied Upon

Petitioner relies on the following references:

Reference	Publication/Patent Number	Exhibit
Aizawa	U.S. Patent Application Publication No. 2002/0188210 A1, filed May 23, 2002, published December 12, 2002.	1006
Inokawa	Japanese Patent Application Publication No. 2006-296564 A, filed April 18, 2005, published November 2, 2006.	1007, 1008[1]
Ohsaki	U.S. Patent Application Publication No. 2001/0056243 A1, filed May 11, 2001, published December 27, 2001.	1014
Mendelson-2006	"A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring," Proceedings of the 28th IEEE EMBS Annual International Conference, 912–915 (2006).	1016
Beyer	U.S. Patent No. 7,031,728 B2 issued April 18, 2006.	1019
Goldsmith	U.S. Patent Application Publication No. 2007/0093786 A1, filed July 31, 2006, published April 26, 2007.	1027
Lo	U.S. Patent Application Publication No. 2004/0138568 A1, filed June 15, 2003, published July 15, 2004.	1028
Mendelson-1988	"Design and Evaluation of a New Reflectance Pulse Oximeter Sensor," Worcester Polytechnic Institution, Biomedical Engineering Program, Worcester, MA 01609; Association for the Advancement of Medical Instrumentation, Vol. 22, No. 4, 1988, 167–173.	1015

Pet. 1–2.

Petitioner also relies on the declaration testimony of Thomas W. Kenny, Ph.D. (Exhibits 1003 and 1047). Patent Owner relies on the

[1] Exhibit 1008 is an English translation of Exhibit 1007.

declaration testimony of Vijay K. Madisetti, Ph.D. (Exhibit 2004). The parties also provide deposition testimony from Dr. Kenny and Dr. Madisetti, including from this and other proceedings. *See* Exs. 1034–1036, 2006–2009, 2027.

F. Asserted Grounds

We instituted an *inter partes* review based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	References/Basis
1–9, 11, 13–15, 19–22, 24–27	103	Aizawa, Inokawa
1–9, 11, 13–15, 19–22, 24–27	103	Aizawa, Inokawa, Ohsaki
16, 27, 28	103	Aizawa, Inokawa, Mendelson-2006
17, 18, 29	103	Aizawa, Inokawa, Mendelson-2006, Beyer
16–18, 27–29	103	Aizawa, Inokawa, Goldsmith, Lo
10	103	Aizawa, Inokawa, Al-Ali
1–9, 11–15, 19–26	103	Mendelson-1988, Inokawa
16, 27, 28	103	Mendelson-1988, Inokawa, Mendelson-2006
17, 18, 29	103	Mendelson-1988, Inokawa, Mendelson-2006, Beyer

II. ANALYSIS

A. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406

(2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of non-obviousness.[2] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

Petitioner identifies the appropriate level of skill in the art as that possessed by a person having "a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information,

[2] The parties do not present objective evidence of non-obviousness based on the final record.

including but not limited to physiological monitoring technologies." Pet. 4–5 (citing Ex. 1003 ¶¶ 21–22). "Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline." *Id.*

Patent Owner does not challenge using Petitioner's asserted level of skill, but notes that "asserted level of skill (1) requires no coursework, training or experience with optics or optical physiological monitors; (2) requires no coursework, training or experience in physiology; and (3) focuses on data processing and not sensor design." PO Resp. 9–10 (citing Pet. 4–5; Ex. 2004 ¶¶ 35–38).

We adopt Petitioner's assessment for the person of ordinary skill in the art ("POSITA") as set forth above, which appears consistent with the level of skill reflected in the Specification and prior art.

C. Claim Construction

For petitions filed on or after November 13, 2018, a claim shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b) (2019). Although both parties contend that no claim term requires express construction (Pet. 4; PO Resp. 9), the substance of the parties' briefing demonstrates that there is a dispute regarding the claim term "cover."

1. "cover"

Each of independent claims 1 and 19 requires "a light permeable cover." Ex. 1001, 44:50, 46:10.

Patent Owner argues that the claimed "cover" excludes "an optically clear adhesive/epoxy" and a "resin on a surface." PO Resp. 45–47. According to Patent Owner, "the '708 Patent distinguishes a resin on a surface from a cover, explaining: 'the cylindrical housing 1430 (and transparent cover 1432) . . . can protect the detectors 1410c and conductors 1412c ***more effectively*** than currently-available ***resin epoxies***.'" *Id.* at 45 (quoting Ex. 1001, 36:37–46).

Patent Owner alleges that Dr. Kenny also "distinguished a sealing resin from a cover, acknowledging a 'layer of sealing resin' is 'one way to protect the components ***without using a cover***.'" *Id.* at 45–46 (quoting Ex. 2009, 395:22–396:17). Patent Owner argues its understanding is consistent with the prior art cited by Petitioner. *Id.* at 46 (citing Ex. 1008 ¶ 103, Fig. 17; Ex. 1023 ¶ 35; Ex. 1012, 5:2–6, Fig. 2B; Ex. 1013 ¶ 32, Fig. 2; Ex. 1027 ¶ 85, Fig. 9B; Ex. 2004 ¶ 104).

Petitioner replies that "there is nothing in the specification or the prosecution history [of the '708 patent] that would lead a [person of ordinary skill in the art] to conclude that 'cover' should be interpreted based on anything other than its plain meaning." Pet. Reply 21 (citing *Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362, 1368 (Fed. Cir. 2012)). That plain meaning, according to Petitioner, is that "a cover is merely 'something that protects, shelters, or guards.'" *Id.* at 21 (quoting Ex. 1050; citing Pet. 74–75; Ex. 1047 ¶ 43). Petitioner argues that Patent Owner's reliance on the '708 patent Specification takes text out of context and, when context is considered, it is clear that "the epoxy resin to which the '708 patent compares its cover is not [an] epoxy cover . . . but rather epoxy that is applied to solder joints." *Id.* at 21–22 (citing Ex. 1001, 36:37–46; Ex. 1047 ¶ 45).

Petitioner also contends that Patent Owner "mischaracterizes Dr. Kenny's deposition testimony to say he agreed that 'sealing resin' is somehow distinguished from a cover." *Id.* at 21. Petitioner contends that Dr. Kenny simply "clarified that using a sealing resin is 'a pretty common way to protect electronic components.'" *Id.* (citing Ex. 2009, 395:22–396:17; Ex. 1047 ¶ 44). Moreover, Petitioner contends that "such extrinsic evidence would not justify departure from plain meaning under *Thorner*." *Id.*

In its Sur-reply, Patent Owner maintains that the '708 patent "specifically ***distinguishes*** a 'resin' on a surface from a 'cover,'" and Petitioner's opposing reading is not persuasive. Sur-reply 19–21.

Upon review of the record, we disagree with Patent Owner's limiting construction of "cover" to exclude epoxy and resin. The plain and ordinary meaning of the term does not support Patent Owner's view. A "cover" ordinarily connotes "something that protects, shelters, or guards." Ex. 1050,[3] 288. That plain and ordinary meaning is consistent with the '708 patent's description of "flex circuit cover 360, which can be made of plastic or another suitable material . . . [and] can cover and thereby protect a flex circuit (not shown)." Ex. 1001, 22:63–65. It also is consistent with the '708 patent's description and illustration of "transparent cover 1432" in Figure 14D, which covers and protects detectors 1410c and conductors 1412c, and which "can be fabricated from glass or plastic, *among other materials*." *See id.* at 36:23–32 (emphasis added), Figs. 14D–14E.

This is not the situation in which a special definition for a claim term has been set forth in the specification with reasonable clarity, deliberateness,

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[3] *Merriam-Webster's Collegiate Dictionary*, 11th ed. (©2005).

and precision, so as to give notice of the inventor's own lexicography. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005); *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Nor do we discern that Patent Owner "demonstrate[d] an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002).

Here, based upon our review of the intrinsic evidence, no such special definition or express disavowal of the term "cover" to exclude epoxy and resin exists. Patent Owner relies on the following description of Figure 14D in that regard:

> *In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432)* forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, *in certain embodiments, the cylindrical housing 1430 can protect* the detectors 1410c and conductors 1412c *more effectively than currently-available resin epoxies*, which are sometimes applied to solder joints between conductors and detectors.

Ex. 1001, 36:37–46 (emphases added). First, the sentence cited by Patent Owner begins with the phrase "[i]n certain embodiments," which indicates the claimed invention is not limited and is open to other embodiments, so there is no lexicography or disavowal here. Second, we agree with Petitioner's reading of this passage as distinguishing the prior art from the claimed invention based on the *location* of the material (applied only to solder joints between conductors and detectors in the prior art, as opposed to covering the conductors and detectors in the invention) and not the *type* of

material. Third, at best, the ’708 patent expresses a preference for a cover to be made of glass or plastic, because such materials provide “more effective[]” protection than resin epoxies that were known when the ’708 patent was filed. *See id.* at 36:39–45. But even this reading recognizes that resin epoxies provide some amount of protection, albeit perhaps a lesser amount than glass or plastic, and are not excluded from forming the material of a cover.

Dr. Kenny’s deposition testimony cited by Patent Owner also does not persuade us that, in the context of the ’708 patent, epoxy or resin is excluded from the material of a cover. Dr. Kenny testifies that “a layer of sealing resin” “[c]ould” be used to protect the electronic components in a sensor (Ex. 2009, 395:22–396:8). He was then asked “So that would be one way to protect the components without using a cover, correct?” to which he answered “[t]here are many ways to protect the elements other than using a cover” and maintained that the proposed combination of prior art has a “cover” to achieve purposes *other than* protecting electronic components, i.e., “to improve adhesion and to improve light gathering for the operation of the system.” *Id.* at 396:9–17. He did not squarely testify that sealing resin may never be a cover.

Accordingly, in the context of the ’708 patent, we do not construe the claimed “cover” to exclude epoxy and resin.

2. Other Claim Terms

Upon consideration of the entirety of the arguments and evidence presented, we conclude no further explicit construction of any claim term is needed to resolve the issues presented by the arguments and evidence of record. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*

Matal, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (claim terms need to be construed "only to the extent necessary to resolve the controversy" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. Obviousness over Aizawa and Inokawa

Petitioner contends that claims 1–9, 11, 13–15, 19–22, and 24–27 of the '708 patent would have been obvious over the combined teachings of Aizawa and Inokawa. Pet. 7–40.

1. Overview of Aizawa (Ex. 1006)

Aizawa is a U.S. patent application publication titled "Pulse Wave Sensor and Pulse Rate Detector," and discloses a pulse wave sensor worn on a user's wrist that detects light output from a light emitting diode and reflected from a patient's artery. Ex. 1006, codes (54), (57).

Figure 1(a) of Aizawa is reproduced below.

FIG. 1 (a)

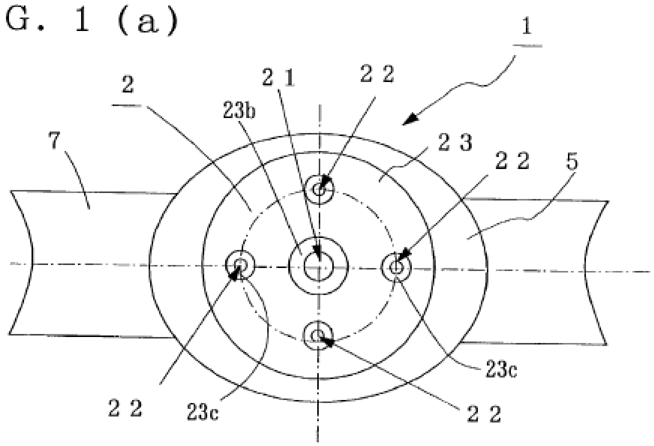


Figure 1(a) is a plan view of a pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(a), pulse wave sensor 2 includes light emitting diode ("LED") 21, four photodetectors 22 symmetrically disposed around LED 21, and holder 23 for storing LED 21 and photodetectors 22. *Id.* Aizawa discloses

that, "to further improve detection efficiency, . . . the number of the photodetectors 22 may be increased." *Id.* ¶ 32, Fig. 4(a). "The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22." *Id.* ¶ 33.

Figure 1(b) of Aizawa is reproduced below.

FIG. 1 (b)

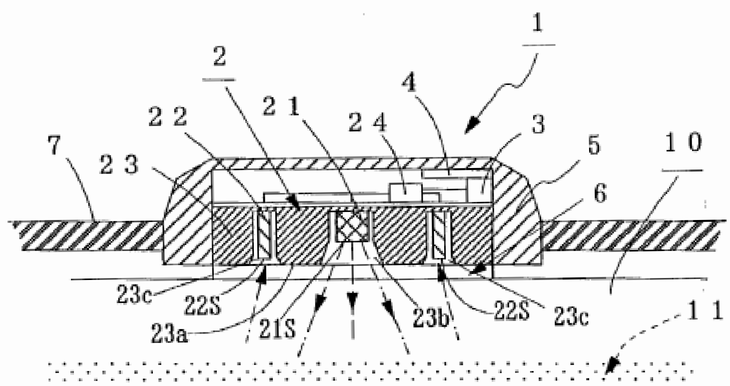


Figure 1(b) is a sectional view of the pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(b), pulse wave sensor 2 includes drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of photodetectors 22. *Id.* Arithmetic circuit 3 computes a pulse rate from the detected pulse wave and transmitter 4 transmits the pulse rate data to an "unshown display." *Id.* The pulse rate detector further includes outer casing 5 for storing pulse wave sensor 2, acrylic transparent plate 6 mounted to detection face 23a of holder 23, and attachment belt 7. *Id.*

Aizawa discloses that LED 21 and photodetectors 22 "are stored in cavities 23b and 23c formed in the detection face 23a" of the pulse wave sensor. *Id.* ¶ 24. Detection face 23a "is a contact side between the holder 23 and a wrist 10, respectively, at positions where the light emitting face 21s of the light emitting diode 21 and the light receiving faces 22s of the photodetectors 22 are set back from the above detection face 23a." *Id.*

Aizawa discloses that "a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 . . . in such a manner that the light emitting face 21s of the light emitting diode 21 faces down (on the wrist 10 side)." *Id.* ¶ 26. Acrylic transparent plate 6 is disposed between holder 23 and the user's wrist 10. *Id.* ¶¶ 23, 26, 30. Furthermore, "belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10." *Id.* ¶ 26. "Since the acrylic transparent plate 6 is provided on the detection face 23a of the holder 23, adhesion between the pulse rate detector 1 and the wrist 10 can be improved, thereby further improving the detection efficiency of a pulse wave." *Id.* ¶ 30.

2. Overview of Inokawa (Ex. 1008)

Inokawa is a Japanese published patent application titled "Optical Vital Sensor, Base Device, Vital Sign Information Gathering System, and Sensor Communication Method," and discloses a pulse sensor device that may be worn on a user's wrist. Ex. 1008, code (54), ¶ 56.[4]

[4] Exhibit 1008 is an English translation of Exhibit 1007. In this Decision, all citations are to the English translation.

Figure 1 of Inokawa is reproduced below.

(FIG. 1)

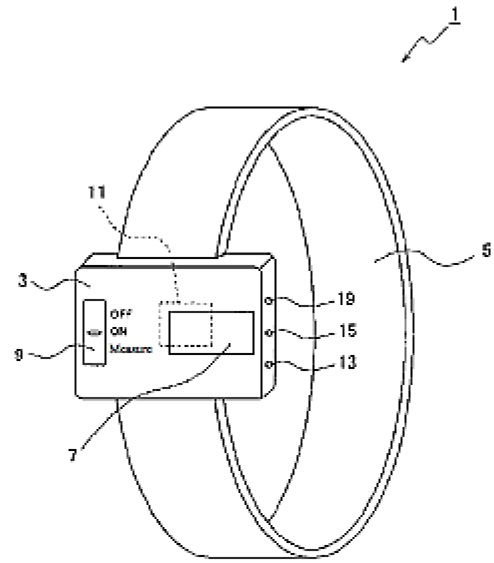


Figure 1 illustrates a perspective view of a pulse sensor. *Id.* ¶ 56. Pulse sensor 1 includes box-shaped sensor unit 3 and flexible annular wristband 5. *Id.* ¶ 57. Sensor unit 3 includes a top surface with display 7 and control switch 9, and a rear surface (sensor-side) with optical device component 11 for optically sensing a user's pulse. *Id.*

Figure 2 of Inokawa is reproduced below.

(FIG. 2)

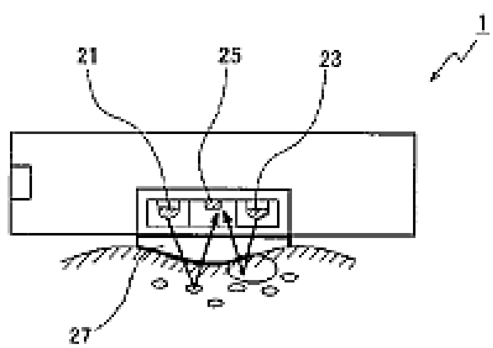


Figure 2 illustrates a schematic view of the rear surface of the pulse sensor. *Id.* ¶ 58. The rear-side (sensor-side) of pulse sensor 1 includes a pair of

light-emitting elements, i.e., green LED[5] 21 and infrared LED 23, as well as photodiode 25 and lens 27. *Id.* In various embodiments, Inokawa discloses that the sensor-side lens is convex. *See id.* ¶¶ 99, 107. Green LED 21 senses "the pulse from the light reflected off of the body (i.e.[,] change in the amount of hemoglobin in the capillary artery)," and infrared LED 23 senses body motion from the change in reflected light. *Id.* ¶ 59. The pulse sensor stores this information in memory. *Id.* ¶ 68. To read and store information, the pulse sensor includes a CPU that "performs the processing to sense pulse, body motion, etc. from the signal . . . and temporarily stores the analysis data in the memory." *Id.* ¶ 69.

Pulse sensor 1 includes lens 27, which "makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD[6]." *Id.* ¶¶ 15, 58. Pulse sensor 1 also uses LEDs 21 and 23 to download data to a base station, as shown in Figure 3, reproduced below.

[5] We understand "LED" to be an acronym for "light emitting diode."
[6] We understand "PD" to be an acronym for "photodiode."

(FIG. 3)

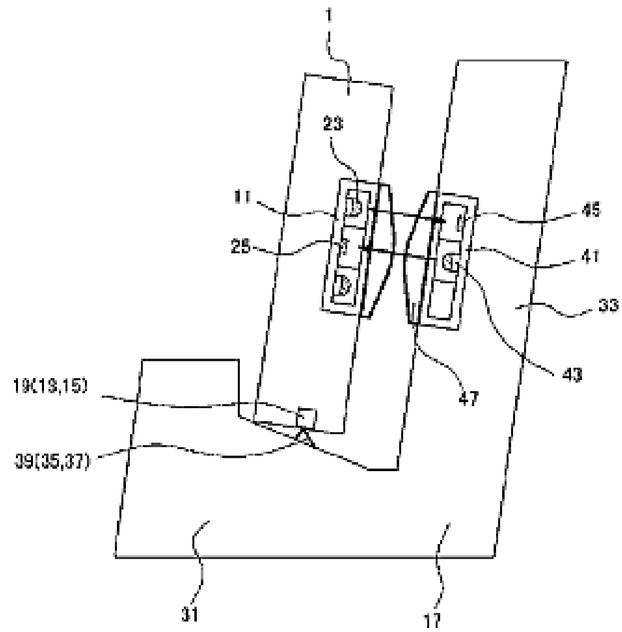


Figure 3 illustrates a schematic view of a pulse sensor mounted to a base device. *Id.* ¶ 60. Pulse sensor 1 is depicted as mounted to base device 17, which "is a charger with communication functionality." *Id.* When so mounted, sensor optical device component 11 and base optical device component 41 face each other in close proximity. *Id.* ¶ 66. In this position, pulse sensor 1 can output information to the base device through the coupled optical device components. *Id.* ¶ 67. Specifically, the pulse sensor CPU performs the controls necessary to transmit pulse information using infrared LED 23 to photodetector 45 of base device 17. *Id.* ¶¶ 67, 70, 76. In an alternative embodiment, additional sensor LEDs and base photodetectors can be used to efficiently transmit data and improve accuracy. *Id.* ¶ 111.

3. Independent Claim 1

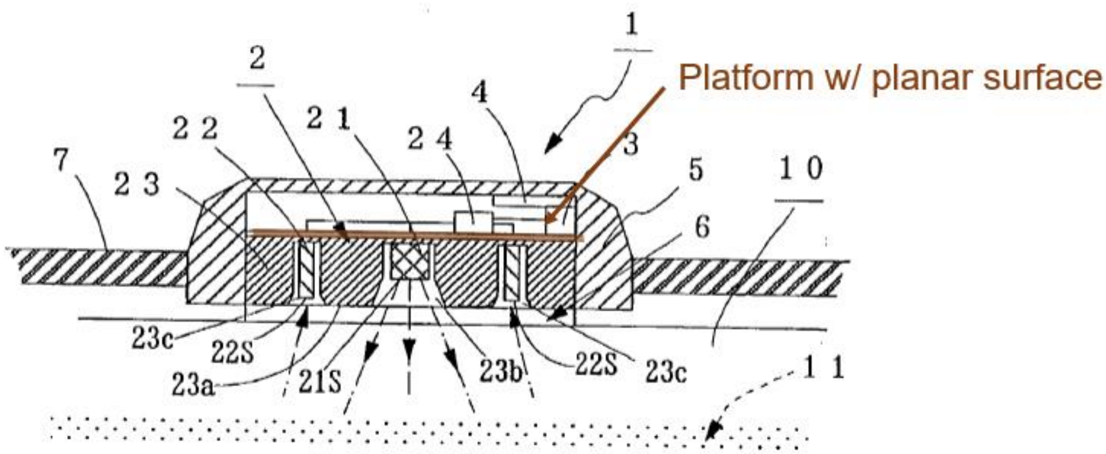
Petitioner contends that claim 1 would have been obvious over the combined teachings of Aizawa and Inokawa. Pet. 12–16 (combination), 16–24 (claim 1).

i. "A noninvasive optical physiological sensing system comprising:"

Based on the final record, the cited evidence supports Petitioner's undisputed contention that Aizawa discloses a measurement device, i.e., a pulse sensor worn on a wearer's wrist. Pet. 16; *see, e.g.*, Ex. 1006 ¶ 2 ("[A] pulse wave sensor for detecting the pulse wave of a subject from light reflected from a red corpuscle in the artery of a wrist of the subject by irradiating the artery of the wrist with light.").

ii. [a] "a platform including a planar surface;"

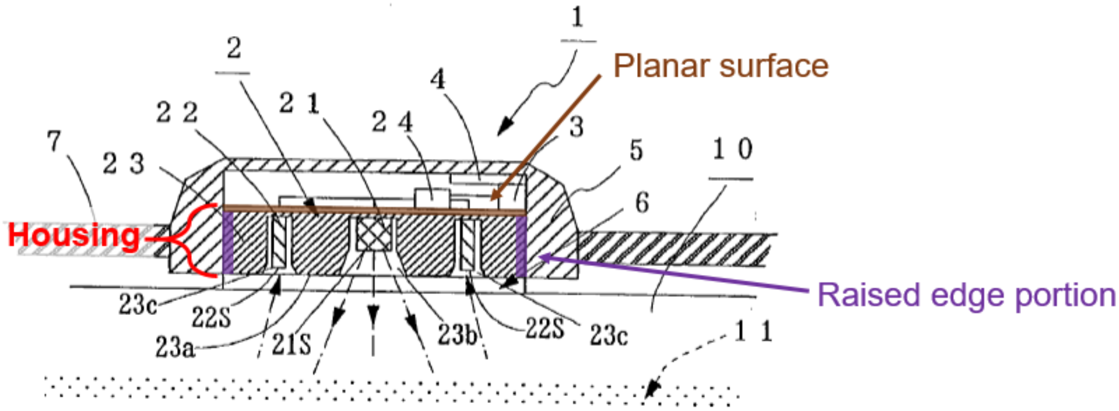
The cited evidence supports Petitioner's undisputed contention that Aizawa discloses holder 23 for storing light emitting diode 21 and photodetectors 22 and a platform including a planar surface on which holder 23 is placed. Pet. 17–18; *see, e.g.*, Ex. 1006 ¶ 23 ("LED 21 . . . for emitting light having a wavelength of a near infrared range"), Figs. 1(a)–(b). Petitioner provides the following annotated Figure 1(b) depicting the planar surface in brown.

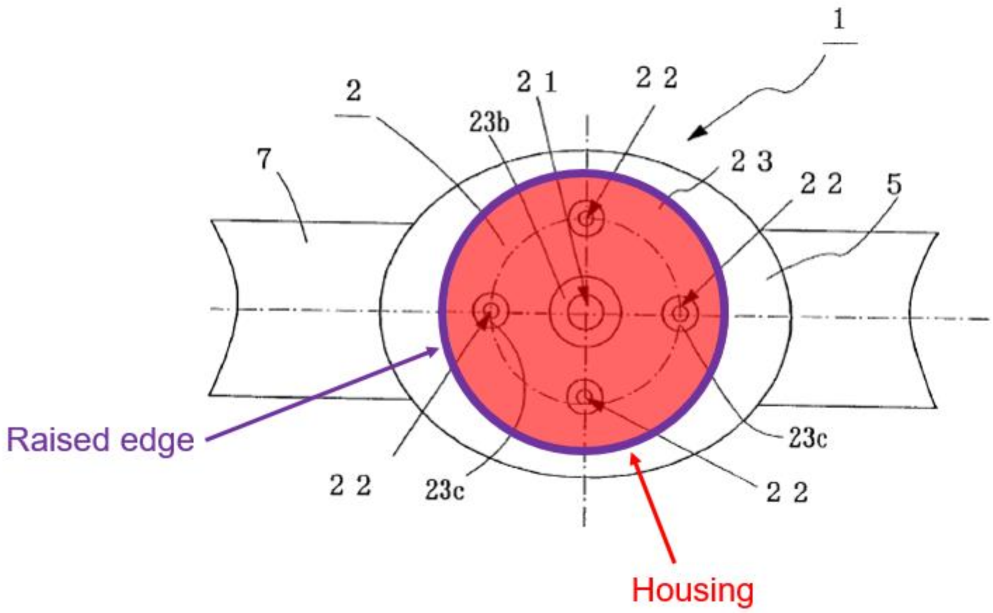


Pet. 18. Annotated Figure 1(b) depicts Aizawa's sensor with the platform with a planar surface depicted in brown. *Id.* Petitioner contends that a person of ordinary skill in the art "would have understood that the various electronic components of Aizawa, including its detectors and emitter, are positioned within the holder 23 and further connected, through the identified platform that supports the holder 23, to a drive circuit 24 on the other side of the holder/platform." *Id.* (citing Ex. 1006 ¶ 23; Ex. 1003 ¶ 75).

iii. [b] "a housing including a raised edge portion extending from and enclosing at least a portion of the planar surface"

The cited evidence supports Petitioner's undisputed contention that Aizawa discloses holder 23, which includes a flat surface and a circular raised edge extending from the surface. Pet. 19; *see, e.g.*, Ex. 1006 ¶ 23 ("holder 23 for storing . . . light emitting diode 21 and the photodetectors 22"), Figs. 1(a)–(b) (depicting holder 23 surrounding each detector 22); Ex. 1003 ¶¶ 76–77. Petitioner provides annotated versions of Aizawa's Figures 1(a) and 1(b), which are reproduced below.





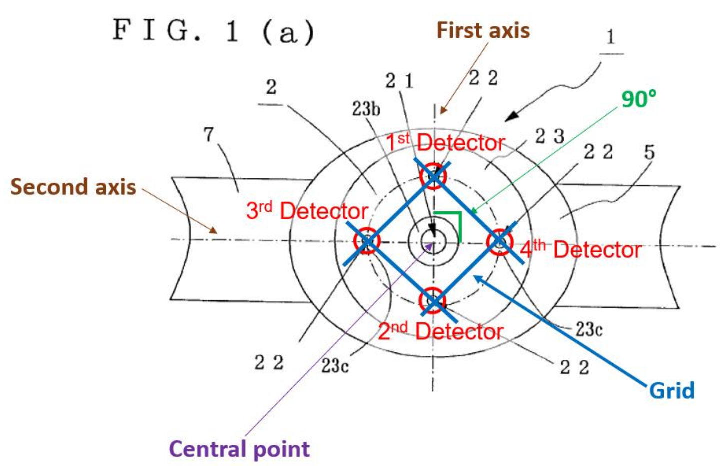
Pet. 19–20. Figures 1(a) and 1(b) depict side and top views of Aizawa's sensor with the housing depicted in red (holder 23), the raised edge depicted in purple, and the planar surface depicted in brown. *Id.*

> *iv.* *[c] "at least four detectors arranged on the planar surface of the platform and within the housing, wherein the at least four detectors are arranged in a grid pattern such that a first detector and a second detector are arranged across from each other on opposite sides of a central point along a first axis, and a third detector and a fourth detector are arranged across from each other on opposite sides of the*

> *central point along a second axis which is perpendicular to the first axis; and"*

The cited evidence supports Petitioner's undisputed contention that Aizawa discloses at least four detectors 22 that are disposed around light emitting diode 21 symmetrically in a perpendicular grid pattern around light emitting diode 21. Pet. 20–21; *see, e.g.*, Ex. 1006 ¶ 23 ("drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of the photodetectors 22"), Fig. 1(a) (depicting detectors 22 spaced apart around LED 21 in a symmetric grid pattern), Fig. 1(b) (depicting detectors 22 connected to a drive circuit 24 on the other side of the housing), ¶ 28 ("the amplified output is converted into a digital signal for the computation of a pulse rate"); Ex. 1003 ¶¶ 78–80.

Petitioner provides annotated Figure 1(a) of Aizawa showing how the four detectors "are arranged relative to a central point and first/second axes in the manner claimed, with the first/second axes being perpendicular to each other." Pet. 22.



Pet. 22. Annotated Figure 1(a) depicts four detectors (in red) arranged in a grid pattern such that the first and second detector form a first axis that is

perpendicular to a second axis formed by the third and fourth detectors. *Id.* We find Petitioner's showing persuasive based on the final record.

v. [d] "the housing including a protruding light permeable cover."

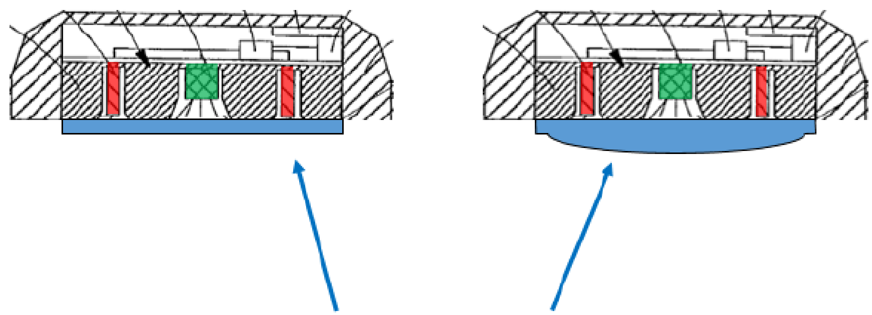
(1) Petitioner's Contentions

Petitioner contends that the cited evidence discloses this limitation. Pet. 12–16, 22–24. Specifically, Petitioner contends that Aizawa discloses a protruding cover in the form of an "acrylic transparent plate" mounted over at least a portion of the housing and to cover the at least four detectors. *Id.* at 22; Ex. 1006 ¶¶ 23, 34 ("[A]crylic transparent plate 6 is provided on the detection face 23a of the holder 23 to improve adhesion to the wrist 10."), Fig. 1(b) (depicting flat, transparent plate 6 between sensor 2 and wrist 10); Ex. 1003 ¶ 83 ("Because the light permeable cover of Aizawa . . . protrudes from the rest of the housing and is designed to be pressed into the skin when worn, it is protruding—and is thus a protruding light permeable cover.").

Petitioner further contends that Inokawa also teaches a protruding light permeable cover and provides motivation for incorporating such a cover into Aizawa. Pet. 13, 23. Specifically, Inokawa's lens 27 is positioned between its sensor and the wearer's skin, which increases the light gathering ability of the sensor. *Id.* at 13, 23; *see, e.g.*, Ex. 1008 ¶¶ 15 ("This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD."), 58 (disclosing "a single photodiode (S-side PD) 25 that receives the reflected light from these [LEDs], and an S-side lens 27"), Fig. 2.

In light of these teachings, Petitioner contends that a person of ordinary skill in the art "would have found it obvious to modify the flat

acrylic plate of Aizawa, as illustrated below, to further Aizawa's objective of enhancing light-collection efficiency," i.e., "by modifying the light permeable cover of Aizawa to include a convex protrusion that acts as a lens." Pet. 13, 23–24.



Pet. 14–15, 23–24; Ex. 1006 ¶¶ 13 (explaining that transparent plate 6 seeks to "improve adhesion" and "improve the detection efficiency of pulse waves"), 30 (same); Ex. 1008 ¶ 15; Ex. 1003 ¶¶ 82–87. Petitioner's annotated and modified Figures depict Aizawa's sensor including its flat transparent plate (left) and a modified version of Aizawa's sensor in which the plate includes a convex protrusion. Pet. 14, 24.

Petitioner contends this modification would have enjoyed a reasonable expectation of success because, for example, Inokawa teaches that the cover may be flat, like that of Aizawa, to reduce scratches, or in the form of a lens, as in Petitioner's proposed modification, to increase light gathering ability. *Id.* at 14–16; *see, e.g.*, Ex. 1008 ¶¶ 15 ("This lens makes it possible to increase the light-gathering ability."), 106 ("[B]ecause the surface of the covers 123, 131 is flat, the surface is less prone to scratches than when the lens protrudes."); Ex. 1003 ¶ 88.

(2) Patent Owner's Response

Patent Owner counters, arguing Aizawa alone "does not '[disclose] a protruding light permeable cover,' as required by claim 1." PO Resp. 15. According to Patent Owner, Petitioner has presented conflicting interpretations and assertions as to whether Aizawa's transparent plate (6) protrudes from holder (23). *Id.* (citing Pet. 9; Ex. 2004 ¶ 49). Patent Owner explains that "Petitioner's argument depends on arbitrarily changing Petitioner's identification of the 'housing' from (1) merely the holder (23) . . . to (2) the holder (23) and the transparent plate (6)." *Id.* at 14. However, Patent Owner argues that even if transparent plate (6) is part of the "housing," "there is no protrusion, as required by claim 1—the transparent plate (6) merely forms a flat face on the 'housing.'" *Id.* at 15.

Patent Owner does not dispute that Inokawa discloses such a protruding light permeable cover, but does argue that Petitioner has not shown that a person of ordinary skill in the art would have been motivated to combine Inokawa's convex lens with Aizawa's sensor. PO Resp. 15–35. According to Patent Owner, "neither Petitioner nor Dr. Kenny explains why a POSITA would have believed that Inokawa's convex lens, which concentrates light to a central detector, would enhance light collection in Aizawa's sensor (and the illustrated combination) with peripheral detectors." *Id.* at 14 (emphasis omitted). Rather, Patent Owner argues that "Petitioner, Dr. Kenny, and the '708 Patent all agree that a POSITA would have understood that Inokawa's protruding surface would direct incoming light towards the center of the sensor," which "undermines Petitioner's proposed combination because Aizawa's detectors are located at the periphery of the sensor." *Id.* at 19. Patent Owner explains that "a POSITA would have believed that Inokawa's protruding surface would direct light ***away*** from the

periphery-located detectors." *Id.* at 20 (citing Ex. 2004 ¶¶ 42–43, 50–59). As such, "a POSITA would have believed that a protruding surface would have undesirably ***decreased*** light-collection efficiency at Aizawa's peripheral detectors, reducing the measured optical signal." *Id.* (citing Ex. 1006 ¶¶ 26, 30; Ex. 2004 ¶ 60). Patent Owner further argues that the '708 patent illustrates how a protruding convex surface focuses light away from the periphery and towards the center. *Id.* at 23–24 (citing Ex. 1001, Fig. 14B).

Patent Owner contends that Dr. Kenny's testimony to the contrary is either contradictory or unsupported. Patent Owner writes that "Dr. Kenny admitted 'one of ordinary skill in the art would expect a diffuse light source encountering a convex lens of the sort that we're contemplating today, would lead to convergence of the light on the opposite side of the lens, in general' and that there would be 'a convergence of most of the light rays.'" *Id.* at 24 (citing Ex. 2007, 423:7–424:18) (emphases omitted). Comparing Dr. Kenny's testimony in the present case to prior testimony in IPR2020-01520, Patent Owner argues that Dr. Kenny's testimony is inconsistent or contradictory. *See id.* at 15–19, 22–26 (comparing prior testimony discussing how such a protruding surface like Inokawa's lens would cause incoming light to condense toward the center). Patent Owner's contention is that Dr. Kenny's "testimony falls far short of establishing a valid motivation to combine Inokawa with Aizawa, much less a reasonable expectation of success," with the "discussion of a reasonable expectation of success focus[ing] almost entirely on manufacturing." *Id.* at 31 (citing Ex. 2004 ¶ 75; Ex. 1003 ¶ 89). This possibility that a person of ordinary skill in the art could manufacture such a sensor, according to Patent Owner, falls short

of showing that such a person would reasonably expect success. *Id.* (citing Ex. 2004 ¶ 75; *In re Stepan Co.*, 868 F.3d 1342, 1347 (Fed. Cir. 2017)).

Patent Owner moreover asserts Petitioner errs in relying on Nishikawa as supporting the unpatentability of claim 1, because Nishikawa is "not identified as part of" the ground, which instead "includes only two references," Aizawa and Inokawa. PO Resp. 32 (citing Pet. 1–2, 15–16; Ex. 1003 ¶¶ 89); *id.* at 33–35 (citing 35 U.S.C. § 312(a)(3); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016)). Patent Owner asserts Dr. Kenny "relies heavily" on Nishikawa, particularly "to inform the specific shape of the cover in his similar combination, which is found nowhere in Aizawa and Inokawa." *Id.* at 32, 34–35 (citing Pet. 23; Ex. 2004 ¶¶ 76–77; Ex. 2006, 179:21–180:13; Ex. 2007, 364:2–13; Ex. 2008, 73:8–12).

Furthermore, in Patent Owner's view, "Petitioner's extensive reliance on Nishikawa makes no sense" because "Nishikawa's device is not a physiological sensor" but rather is "an encapsulated LED" that "directs ***outgoing*** light through the encapsulation material and thus focuses on the emission of light, not the detection of an optical signal." PO Resp. 34 (citing Ex. 1023, code (57), ¶¶ 3, 32, 35; Ex. 2004 ¶ 78). Patent Owner contrasts such disclosure with Aizawa and Inokawa, both of which "detect[] ***incoming*** light that passes through the cover and reaches the detectors," and which have a "drastically" smaller scale than Nishikawa's LEDs. *Id.* (citing Ex. 1008, Fig. 2; Ex. 2004 ¶ 78).

(3) Petitioner's Reply

In reply, Petitioner reiterates that "a POSITA would have been motivated to incorporate 'an Inokawa-like lens into the cover of Aizawa to

increase the light collection efficiency. . . .'" Pet. Reply 2–3 (quoting Pet. 12–14; Ex. 1003 ¶¶ 82–87). Petitioner counters Patent Owner's arguments by contending that Patent Owner has a "misinformed understanding of Inokawa's lens" and "lenses in general." *Id.* at 3 (citing PO Resp. 12). According to Petitioner, "a POSITA would understand that Inokawa's lens generally improves 'light concentration at pretty much all of the locations under the curvature of the lens,' as opposed to only at a single point at the center as asserted by Masimo." *Id.* (citing Ex. 2006, 164:8–16).

According to Petitioner, part of Patent Owner's misunderstanding may be due to Patent Owner ignoring the principle of reversibility. *Id.* at 4–14. For example, Petitioner contends that Patent Owner and Dr. Madisetti "ignore[] the well-known principle of reversibility," by which "a ray going from P to S will trace the same route as one from S to P." *Id.* at 4 (emphasis omitted) (citing, e.g., Ex. 1052,[7,8] 84, 87–92; Ex. 1049, 101, 106–111; Ex. 1047 ¶¶ 10–18). Petitioner contends that Dr. Madisetti was evasive when he was asked to apply the reversibility principle to the combination of Aizawa and Inokawa in this case. Pet. Reply 6 (citing Ex. 1034, 89:12–19). Petitioner further contends that, "based at least on the principle of reversibility," one of ordinary skill in the art "would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would

[7] Eugene Hecht, *Optics* (2nd ed. 1990).

[8] It is apparent that the page numbering identified by Petitioner for Exhibit 1052 refers to the document's native page numbering and not the page numbering of the exhibit appearing at the bottom, middle of each page. For clarity and consistency, in this Decision, we also use the same page numbering as Petitioner for Exhibit 1052.

similarly benefit from the enhanced light-gathering ability of an Inokawa-like lens." *Id.* at 9 (citing Ex. 1047 ¶ 22).

Petitioner also asserts that Patent Owner and Dr. Madisetti overlook the fact that light rays reflected by body tissue in the user's wrist, to be received by detectors in either Aizawa's or Inokawa's pulse sensor, will be "scattered" and "diffuse" and, therefore, will approach the detectors "from various random directions and angles." Pet. Reply 9–10, 13 (annotating Inokawa's Fig. 2 to illustrate the cause and nature of the back-scattering); Ex. 1047 ¶¶ 25–26, 31. This scattered and diffuse light, according to Petitioner, means that Inokawa's "lens cannot focus all incoming light toward the sensor's center," as Patent Owner would have it. Pet. Reply 9 (citing Ex. 1047 ¶ 23; Ex. 2006, 163:12–164:2). Petitioner asserts this is due to Snell's law, and provides several illustrations to illustrate why. *Id.* at 9–15 (citing, e.g., Ex. 1047 ¶¶ 23–34).

Due to the random nature of this scattered light, Petitioner explains that one of ordinary skill in the art would have understood that a convex cover "provides a slight refracting effect, such that light rays that may have missed the detection area are instead directed toward that area." Pet. Reply 10 (citing Ex. 1047 ¶¶ 25–26). Petitioner applies this understanding to Aizawa, and contends that using a lens with a convex protrusion in Aizawa would "enable backscattered light to be detected within a circular active detection area surrounding" a central light source. *Id.* (citing Ex. 1051, 86, 90).

Moreover, Petitioner dismisses the applicability of Figure 14B of the '708 patent as illustrating the operation of a *transmittance*-type of sensor that measures the attenuation of collimated light transmitted through the

user's body tissue, rather than the *reflectance*-type sensor of Aizawa. *Id.* at 11–13 (citing, e.g., Ex. 1001, 35:65–67; Ex. 1047 ¶¶ 27–31).

Petitioner further maintains that contrary to Patent Owner's argument, Petitioner's illustrations of the light-focusing properties of a convex lens discussed in the Petition filed in IPR2020-01520 (Ex. 2019, 39) and relied upon by Dr. Kenny (Ex. 2020, 119–120) do not demonstrate "that a convex lens directs all light to the center." Pet. Reply 15 (citing PO Resp. 15–17). Petitioner contends these illustrations, instead, "are merely simplified diagrams included to illustrate . . . one example scenario (based on just one ray and one corpuscle) where a light permeable cover can 'reduce a mean path length of light traveling to the at least four detectors'" as recited in claim 12 of the patent challenged in that proceeding. *Id.* (citing, e.g., Ex. 1047 ¶ 34).

(4) Patent Owner's Sur-reply

Patent Owner asserts that Petitioner's Reply improperly presents several new arguments, relying on new evidence, as compared with the Petition. *See, e.g.*, Sur-reply 1 ("new optics theories" and "new arguments"), 2, 6, 7, 9, 10, 12, 13.

Patent Owner also contends that Petitioner mischaracterizes Patent Owner's position, which is not that Inokawa's lens with a convex protrusion "would direct '***all***' light 'only at a ***single point*** at the center'" of the sensor. *Id.* at 2 & n.2 (quoting Pet. Reply 3; citing, e.g., Ex. 2027, 63:7–64:6, 94:20–96:1, 96:18–97:7). Patent Owner's position, rather, is that Inokawa's lens condenses more light (not necessarily all light) "***towards the center*** of the sensor" as compared to a flat surface. *Id.* at 2 (quoting PO Resp. 19; citing, e.g., Ex. 2004 ¶¶ 34, 43, 51, 53–54, 57, 67).

Patent Owner moreover asserts "[t]here can be no legitimate dispute that a convex surface directs light centrally (and away from the periphery)." Sur-reply 3–6 (citing PO Resp. 15–18; Ex. 2006, 86:19–87:6, 164:8–16, 170:22–171:5, 202:11–204:20; Ex. 2020 ¶¶ 119, 200; Ex. 2027, 181:9–182:5). Patent Owner contends that Petitioner's argument "that Inokawa would improve light-gathering at all locations, ***regardless*** of the location of the LEDs and detectors" is belied by Dr. Kenny's testimony that "Inokawa's benefit would ***not*** be clear if Inokawa's LEDs and detectors were moved" and "confirmed that a convex surface would direct light toward the center of the underlying sensor." *Id.* at 6 (citing Pet. Reply 3–4; Ex. 2006, 86:19–87:6, 202:11–204:20).

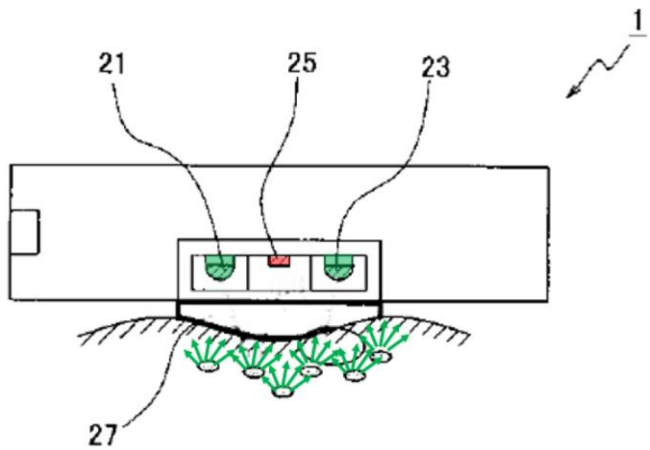
Patent Owner argues that Petitioner's discussion of the principle of reversibility is "irrelevant" because it "assumes ideal conditions that are not present when tissue scatters and absorbs light." Sur-reply 6–8 (citing Ex. 2027, 17:12–19:2, 29:11–30:7, 31:8–32:3, 38:17–42:6, 207:9–209:21, 210:8–6). The random nature of backscattered light, in Patent Owner's view, "hardly supports Petitioner's argument that light will necessarily travel the same paths regardless of whether the LEDs and detectors are reversed," and is irrelevant to the central issue presented here of "whether a convex surface—***as compared with a flat surface***—would collect and focus additional light on Aizawa's peripherally located detectors." *Id.* at 8–9 (citing Ex. 2027, 212:3–14).

Patent Owner also argues that Petitioner's position that a convex cover will provide a "***slight*** refracting effect," "directly undermines Petitioner's provided ***motivation*** to combine," i.e., to enhance light collection efficiency. *Id.* at 10–11.

(5) Analysis

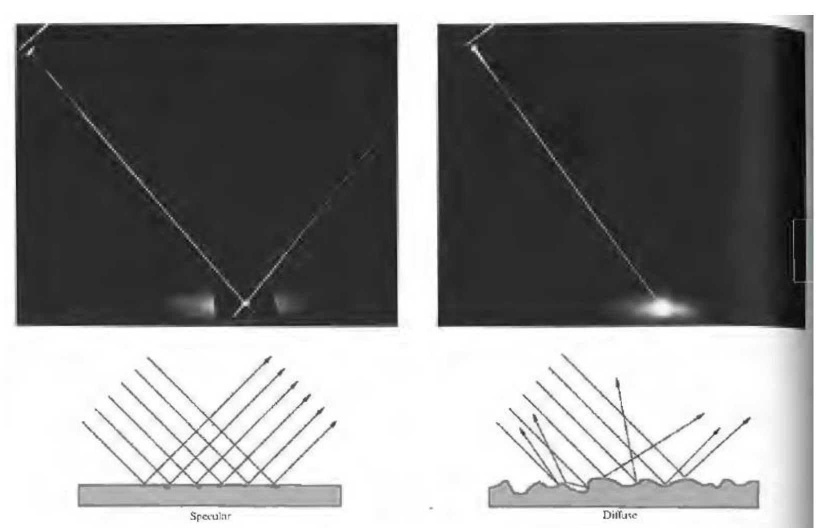
Upon review of the foregoing, we conclude that a preponderance of the evidence supports Petitioner's view that it would have been obvious to modify Aizawa's cover 6 to include a convex lens or protrusion like that taught in Inokawa, in order to increase the amount of backscattered light that will be received by Aizawa's four peripheral detectors 22, as compared with Aizawa's existing flat cover.

Aizawa's and Inokawa's pulse sensors both gather data by emitting light into the user's wrist tissue, and collecting light that reflects back to the sensor from the user's tissue. *See, e.g.*, Ex. 1006, Figs. 1(b), 2 (sensor 2 has emitter 21 and four detectors 22, all facing a user's wrist 10); Ex. 1008, Figs. 1, 2 (sensor 1 has two emitters 21, 23 and one detector (photodiode 25), all facing the user's wrist when held in place by wristband 5). Dr. Kenny testifies, and Patent Owner agrees, that the reflection of this light by the user's wrist tissue randomizes the propagation direction of the reflected light rays. *See* Ex. 1003 ¶¶ 82–87; Ex. 1047 ¶¶ 14–15; Ex. 2020 ¶ 128; Sur-reply 7 ("Even Petitioner admits that tissue randomly scatters and absorbs light rays."). This reflection principle is illustrated by Dr. Kenny's annotations to Inokawa's Figure 2 reproduced below:



Here, Dr. Kenny has modified Inokawa's Figure 2 (1) by removing two black arrows, (2) by coloring Inokawa's light detector in red and Inokawa's two light emitters in green, and (3) by adding several green arrows to illustrate the various directions that light rays may be directed after impinging on and reflecting off different tissues in the user's wrist. Ex. 1047 ¶ 32.

This randomized direction of reflected light rays results in backscattered light that is diffuse, rather than collimated, in nature. Figure 4.12 of Exhibit 1052 illustrates the difference between diffuse and collimated light, and is reproduced below:

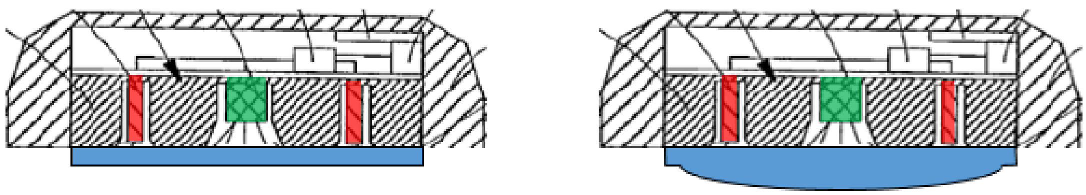


This figure provides at left a photograph and an illustration showing incoming collimated light reflecting from a smooth surface, and at right a photograph and an illustration of incoming collimated light reflecting from a rough surface. *See* Ex. 1052, 87–88. The smooth surface provides specular reflection, in which the reflected light rays are collimated like the incoming light rays. *See id.* By contrast, the rough surface provides diffuse reflection, in which the reflected light rays travel in random directions. *See id.*

This diffuse nature of the light reflected from the user's wrist tissue, which both Aizawa and Inokawa aim to collect to generate pulse data, suggests that a lens might be useful to increase the amount of collected light and thereby increase the reliability of the pulse data generated using the collected light. Indeed, that is taught by Inokawa. Inokawa describes using its lens 27 to "increase the light-gathering ability" of Inokawa's light photodiode or detector 25.[9] Ex. 1008 ¶¶ 15, 58. Furthermore, there is also no dispute that Inokawa's lens 27 is understood to be shaped as a convex protrusion. *See, e.g.*, Ex. 1003 ¶¶ 84–85 (characterizing Inokawa as teaching a "convex protrusion that acts as a lens"); PO Resp. 1 (describing Inokawa as teaching a "convex lens"). Thus, Inokawa demonstrates that it was known in the art to use a lens comprising a protrusion to focus diffuse light reflected from body tissue on to the light detecting elements of a wrist-worn pulse sensor, and to increase the light gathered by the sensor thereby improving the device's calculation of the user's pulse.

[9] Although Inokawa refers to the "LED" such as emitters 21, 23 in that regard (*id.* ¶ 15), rather than photodiode 25, it is undisputed that photodiode 25 is the only component of Inokawa's sensor 1 that gathers light.

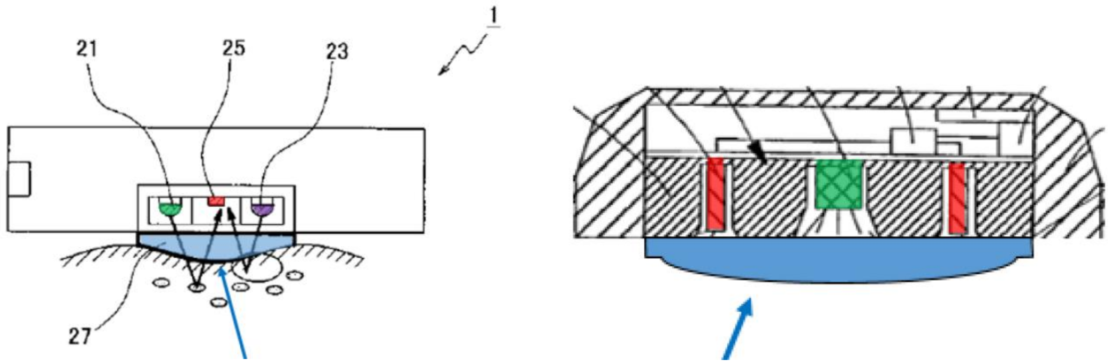
A preponderance of the evidence supports Petitioner's view that it would have been obvious for a person of ordinary skill in the art to apply Inokawa's lens technology to Aizawa's wrist-worn pulse sensor, to similarly improve its light collection as compared to Aizawa's existing flat cover. That is illustrated by the following annotated figures provided by Dr. Kenny:



The illustration at left modifies Aizawa's Figure 1(b) to color Aizawa's emitter in green, its detectors in red, and Aizawa's existing flat cover in blue; the illustration on the right includes Aizawa's Figure 1(b) with the same color coding, but wherein the flat cover is modified to incorporate a convex protrusion that covers Aizawa's peripheral light detectors and central light emitter. *See* Ex. 1003 ¶ 87. We are persuaded by Dr. Kenny's testimony that Snell's law indicates that "light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover," and is especially true "in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source." Ex. 1047 ¶ 26; *see also id.* ¶¶ 23–26.

Patent Owner correctly notes that Inokawa's single detector 25 is located in the central portion of Inokawa's sensor 1, whereas Aizawa's four detectors 22 are located towards the periphery of Aizawa's sensor 2. *Compare* Ex. 1008, Fig. 2, *with* Ex. 1006, Figs. 1(a)–1(b). Nevertheless, Petitioner's proposed modification of Aizawa takes that arrangement into

account, as can be seen by the following comparison between Inokawa's sensor and Petitioner's proposed modification of Aizawa's sensor:



The illustration at left annotates Inokawa's Figure 2 to identify the central detector in red and the lens in blue (*see* Ex. 1003 ¶ 85), and the illustration at right annotates Petitioner's proposed modification of Aizawa to illustrate the peripheral detectors in red and the lens in blue (*see id.* ¶ 87). As can be seen, the lenses are not identical. In Inokawa, the lens's curvature is most pronounced at the center of the lens near the central detector, and in the proposed modification to Aizawa, the lens's curvature is most pronounced at the edges of the lens near the peripheral detectors. Thus, Dr. Kenny's proposed modification of Aizawa takes Inokawa's general teaching of using a convex protrusion lens to increase the amount of incoming light directed to a light detector, and applies it to the four light detectors of Aizawa. *See, e.g.*, Ex. 1003 ¶ 87 ("[A] POSITA would have found it obvious to combine the teachings of Aizawa and Inokawa such that the flat cover (left) of Aizawa is modified to include a lens/protrusion (right) as per Inokawa in order to 'increase the light-gathering ability,'" and "allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities."); *id.* ¶¶ 82–89; Ex. 1047 ¶¶ 7–34.

We are cognizant of Patent Owner's contention that Petitioner's ground "improperly" relies upon a reference, Nishikawa, that was not identified as a part of the ground of unpatentability. PO Resp. 32–33. As Patent Owner observes, Dr. Kenny characterizes his testimony as being "***inspired*** by" or "motivated" in part based on Nishikawa's disclosure when it comes to the shape of a convex lens. *See, e.g.*, PO Resp. 32–33 (citing, e.g., Ex. 2007, 364:2–13; Ex. 2008, 73:8–12) (emphasis omitted). We, however, disagree with Patent Owner that any impropriety arises from Dr. Kenny's contemplation of the teachings of Nishikawa in connection with the shape of a lens for a physiological sensor. The nature of Petitioner's and Dr. Kenny's consideration of Nishikawa is explained in cited portions of Dr. Kenny's declaration, even if Nishikawa is not listed as a third reference in the identification of the ground. *See* Ex. 1003 ¶ 89 ("[M]any prior art references of this period, such as Nishikawa (shown below) demonstrate exactly how such a lens [as taught by Inokawa] may be incorporated into a molded cover."); Pet. 15–16. Indeed, it follows readily from the Petition that a skilled artisan would have appreciated that Nishikawa's teachings provide insight as to how "the transparent acrylic material used to make Aizawa's plate can be readily formed into a lens [structure] as in Inokawa." Pet. 15. Nishikawa describes how its "lens unit 50" can be a transparent resin formed in the shape illustrated in Figure 6 by injection molding. Ex. 1023 ¶¶ 22, 32, 35. Dr. Kenny also explains that Nishikawa's lens shape design "is intended to provide curvature in the lens where it can do the most good and otherwise try to avoid excess use of material in order to create curvature in locations where it wouldn't do any good." Ex. 2006, 179:21–180:13.

Moreover, we observe that a rejection based on obviousness "require[s] an analysis that reads the prior art in context, taking account of 'demands known to the design community,' 'the background knowledge possessed by a person having ordinary skill in the art,' and 'the inferences and creative steps that a person of ordinary skill in the art would employ.'" *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (quoting *KSR*, 550 U.S. at 418). Furthermore, record evidence can be useful to "demonstrate the knowledge and perspective of one of ordinary skill in the art." *Id.*; *see also Ariosa Diagnostics v. Verinata Health Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) ("Art can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness.").

As noted above, Dr. Kenny makes clear that his view as to obviousness of the claims of the '708 patent was "inspired by" or "motivated" in part by Nishikawa's teachings as to shapes generally known to those in the art of manufacturing a lens. *See, e.g.*, Ex. 2007, 364:2–13; Ex. 2008, 73:12–21. We conclude that the record establishes that Nishikawa's teachings are representative of background knowledge of one of ordinary skill in the art and provide context and perspective of a skilled artisan as to the type of shapes available for a convex protruding surface, such as that disclosed in Inokawa. That Dr. Kenny considered record evidence cited in the Petition as informing his view of what a skilled artisan would understand as to known types of lens shapes does not establish, in our view, any impropriety as part of that ground.

Patent Owner additionally asserts, and Dr. Madisetti testifies, that Petitioner's combination of Aizawa and Inokawa is "problematic" because it overlooks the "small" size of Aizawa's detectors 22 and the openings or

cavities 23c in which they are housed. *See* PO Resp. 21–22 (citing Ex. 1006, Fig. 1(a); Ex. 2004 ¶ 65). Patent Owner, however, does not articulate what significance the size of Aizawa's detector components have in the obviousness evaluation based on the teachings of the prior art.

We additionally do not agree with Patent Owner's argument that Petitioner's Reply presents new arguments and evidence that should have been first presented in the Petition. The Petition proposed a specific modification of Aizawa to include a convex protrusion in the cover, for the purpose of increasing the light gathering ability of Aizawa's device. *See, e.g.*, Pet. 12–16. Patent Owner, in its Response, then challenged that contention with several arguments that Petitioner's proposed convex protrusion would not operate in the way the Petition alleged. *See, e.g.*, PO Resp. 15–35. In its Reply, Petitioner provided arguments and evidence attempting to rebut the contentions in the Patent Owner Response. *See* PTAB Consolidated Trial Practice Guide (Nov. 2019),[10] 73 ("A party also may submit rebuttal evidence in support of its reply."). The Reply does not change Petitioner's theory for obviousness; rather, the Reply presents more argument and evidence in support of the same theory for obviousness presented in the Petition. *Compare* Pet. 12–16, *with* Pet. Reply 2–13.

Patent Owner finally argues that a conclusion of obviousness "strains credibility" because the level of ordinary skill in the art (*see supra* Section II.B) does not require specific education or experience with optics or optical physiological monitors. *See, e.g.*, PO Resp. 30. We disagree. Concerning motivation, an ordinarily skilled artisan would have readily appreciated from the record at hand that: (1) Aizawa's detector 1 operates

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[10] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

by gathering light data with its photodetectors 22; (2) a lens was known to focus the light on photodetectors; and (3) optical lenses may be formed by providing a convex protrusion in the lens to focus light. Indeed, Inokawa discloses such utility, function, and structure as a part of its convex lens. *See, e.g.*, Ex. 1008 ¶¶ 15, 58, Fig. 2. We are persuaded that a person of ordinary skill in the art would have understood these general concepts of optics.

Concerning reasonable expectation of success, we rely on Dr. Kenny's testimony that a person of ordinary skill in the art would have understood that "by positioning a lens above the optical components of Aizawa . . . the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities," and "would have found it obvious to combine the teachings of Aizawa and Inokawa such that the flat cover (left) of Aizawa is modified to include a lens/protrusion (right) as per Inokawa in order to 'increase the light-gathering ability.'" *See, e.g.*, Ex. 1003 ¶ 87; Ex. 2006, 179:21–180:13, 202:11–20.

Thus, we conclude that one of ordinary skill in the art would have had adequate reason to replace Aizawa's flat cover 6 with a cover comprising a convex protrusion, to improve light detection efficiency, and would have had a reasonable expectation of success in doing so.

vi. Summary

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 would have been obvious over the cited combination of references.

4. Independent Claim 19

Independent claim 19 consists of limitations that are substantially similar to elements [a]–[d] of claim 1. *Compare* Ex. 1001, 44:36–50, *with id.* at 45:53–46:11 (reciting a "housing including a raised wall protruding"). In asserting that claim 19 also would have been obvious over the combined teachings of Aizawa and Inokawa, Petitioner refers to substantially the same contentions presented as to claim 1. *See* Pet. 35–38; Ex. 1003 ¶¶ 110–115.

Patent Owner does not present any argument for this claim other than those we have already considered with respect to independent claim 1. PO Resp. 11–35.

For the same reasons discussed above, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 19 would have been obvious over the cited combination of references. *See supra* II.D.3.i–v; Ex. 1003 ¶¶ 110–115.

5. Dependent Claims 2–9, 11, 13–15, 20–22, and 24–27

Petitioner presents undisputed contentions that claims 2–9, 11, 13–15, 20–22, and 24–27, which depend directly or indirectly from independent claim 1 or 19, are unpatentable over the combined teachings of Aizawa and Inokawa, and provides arguments explaining how the references teach the limitations of these claims. Pet. 24–35, 38–40; Ex. 1003 ¶¶ 90–109, 116–122.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claim 1. PO Resp. 35 ("The Petition fails to establish that independent claims 1 and 19 would have been obvious in view of [the first ground]'s cited references

and thus fails to establish obviousness as to any of the challenged dependent claims.") (citing Ex. 2004 ¶ 79).

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that claims 2–9, 11, 13–15, 20–22, and 24–27 would have been obvious over the combined teachings of the cited references and as supported by the testimony of Dr. Kenny.

E. Obviousness over Aizawa, Inokawa, and Ohsaki

Petitioner argues claims 1–9, 11, 13–15, 19–22, and 24–27 of the '708 patent would have been obvious over Aizawa, Inokawa, and Ohsaki. Pet. 2, 40–43. Patent Owner opposes. PO Resp. 35–39. We conclude a preponderance of the evidence supports Petitioner's assertions as to these challenged claims. We begin our analysis with a brief summary of Ohsaki, then we address the parties' contentions.

1. Ohsaki Disclosure

Ohsaki discloses a pulse wave sensor attached to the back side of the user's wrist. Ex. 1014, codes (54), (57). Figures 1 and 2 are reproduced below:

FIG. I

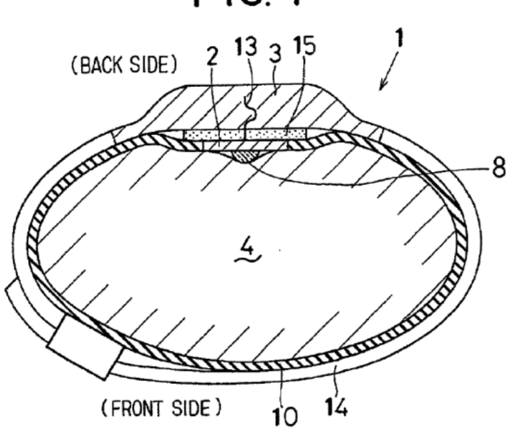


FIG. 2

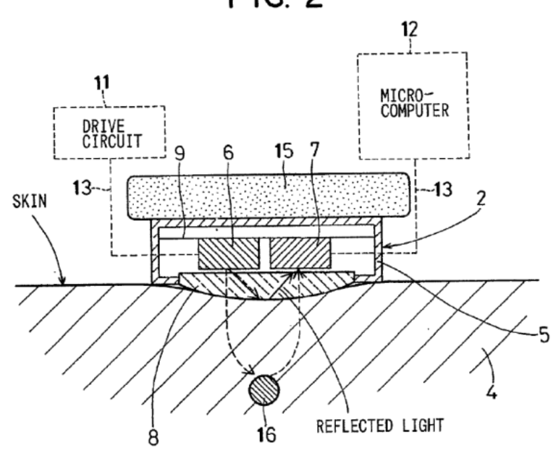


Figure 1 is a cross-sectional view of pulse wave sensor 1 attached on a user's wrist 4. *Id.* ¶¶ 12, 16, 18. Figure 2 is a schematic diagram of detecting element 2 of sensor 1 on wrist 4, and associated electronics. *Id.* ¶¶ 13, 17.

Figure 1 illustrates how detecting element 2 is attached to the back side of the wrist. In this context, the wrist's "back" side is the side opposite to the user's palm, and the wrist's "front" side is the palm side of the hand. *See, e.g.*, *id.* ¶¶ 5–6, 16.

Detecting element 2 comprises a light emitter (LED 6) and a light detector (photodetector 7) for optically interrogating the user's wrist 4 tissue to detect a pulse wave of the user. *See id.* ¶¶ 3, 7–8, 16, 20, 22. Translucent board 8 of element 2 has "a convex surface . . . in intimate contact with the surface of the user's skin," and "[t]hereby it is prevented that the detecting element 2 slips off the detecting position of the user's wrist 4." *Id.* ¶¶ 9, 17–18, 25.

Figures 3A–3B provide test data comparing the performance of a pulse wave sensor depending on whether it is mounted to the back side or the front side of the user's wrist. *See id.* at Figs. 3A–3B, ¶¶ 14, 23–24. Figures 4A–4B provide test data comparing the performance of a pulse wave sensor depending on whether translucent board 8 is convex (as shown in Figures 1 and 2) or flat. *See id.* at Figs. 4A–4B, ¶¶ 15, 25.

2. Claim 1

Petitioner provides arguments and evidence, including testimony from Dr. Kenny, in support of Petitioner's contention that claim 1 is unpatentable as having been obvious over Aizawa, Inokawa, and Ohsaki. Pet. 40–43; Ex. 1003 ¶¶ 64–65, 123–127. Patent Owner provides arguments and

evidence in opposition, including testimony from Dr. Madisetti. PO Resp. 35–39; Ex. 2004 ¶¶ 80–86.

This ground relies on the same prior art as in the prior ground, then adds Ohsaki as providing a further motivation for modifying Aizawa's flat plate 6 to have a convex protrusion. *See* Pet. 40–43; Ex. 1003 ¶¶ 123–127. Petitioner asserts "Ohsaki teaches that adding a convex surface to the light permeable cover (*i.e.*, [Ohsaki's] translucent board 8) can help prevent the device from slipping on the tissue when compared to a flat cover" such as Aizawa's plate 6. Pet. 42–43 (citing Ex. 1014 ¶ 25); Ex. 1003 ¶ 125. Petitioner asserts that Aizawa, similarly to Ohsaki, "seeks to prevent slippage between the device and the user's wrist—and pursues this objective by pressing its . . . [plate 6] and trying to improve 'adhesion between the wrist 10 and the pulse rate detector 11.'" Pet. 43 (citing Ex. 1006 ¶¶ 26, 30); Ex. 1003 ¶ 125. Dr. Kenny testifies a POSITA "would have recognized that Ohsaki's addition of a convex protrusion to its light permeable cover could be similarly implemented in Aizawa's device to help achieve the two references' shared goal of minimizing slippage," which "would have allowed Aizawa's sensor device to remain better adhered to the skin and thereby increase its light-collecting efficiency." Ex. 1003 ¶¶ 126, 142 (citing Ex. 1006 ¶¶ 26, 30; Ex. 1014 ¶ 25); Pet. 42–43.

Patent Owner argues in opposition that the Petition is fatally deficient because it is "unclear as to whether a POSITA would have incorporated Inokawa's lens or Ohsaki's translucent board" in Aizawa. PO Resp. 36; Ex. 2004 ¶ 80. We disagree. The first ground relies on Inokawa as providing a first motivation for adding a protrusion to Aizawa's flat cover: to direct more light to Aizawa's detectors 22. *See supra* Section II.D.3.v. This ground relies additionally on Ohsaki as providing a second, and

independent, motivation for adding a protrusion to Aizawa's flat cover: to reduce slippage between Aizawa's device and the user's wrist. *See* Pet. 42–43. Neither ground seeks to bodily incorporate Inokawa's lens or Ohsaki's translucent board into Aizawa's device, and this is not required for obviousness. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

Patent Owner next contends that Patent Owner's various arguments opposing first ground also apply to this ground. *See* PO Resp. 35–36; Ex. 2004 ¶ 82. For the reasons provided in Section II.D.3 above, Patent Owner's arguments opposing the first ground based on Aizawa and Inokawa are unavailing.

Patent Owner further asserts "a POSITA would have understood that Ohsaki's board would not prevent slippage with Aizawa's sensor." PO Resp. 37 (section heading modified). According to Patent Owner, Ohsaki indicates "its protruding surface must have ***longitudinal directionality***" such that "one must orient its longitudinal convex surface with the longitudinal direction of the user's arm." PO Resp. 37 (citing Ex. 1014 ¶ 19); Ex. 2004 ¶ 83. Patent Owner argues Aizawa's detector 1, by contrast, uses a circular arrangement of four detectors 22 around one emitter 21, and "Aizawa specifically ***distinguishes*** its sensor from linear sensors such as Ohsaki's." PO Resp. 37 (citing Ex. 1006, code (57), ¶¶ 9, 27, 36; Ex. 1014 ¶ 19; Ex. 2008, 165:20–166:5); Ex. 2004 ¶ 84. Patent Owner concludes a "POSITA would not have believed Ohsaki's longitudinal protruding surface would benefit Aizawa's sensor" due to this difference. PO Resp. 38; Ex. 2004 ¶ 85.

Patent Owner moreover argues Ohsaki's "protruding surface only prevents slipping on the backhand side (i.e., watch-side) of the user's wrist," and "Ohsaki's sensor has 'a tendency to slip off' if it is on the palm side of

the user's wrist." PO Resp. 37 (citing Ex. 1014 ¶¶ 23–24, Figs. 3A–3B); Ex. 2004 ¶ 83. Patent Owner asserts Aizawa's detector 1, by contrast, is held against the front side of the user's wrist to be close to the artery there, and "Aizawa reports that on the ***palm side*** of the wrist, a ***flat surface*** improves adhesion." PO Resp. 37–38 (citing Ex. 1006, Figs. 2, 3, code (57), ¶¶ 2, 9, 13, 26–28, 30, 34, 36); Sur-reply 14–15 (similarly citing Ex. 1006); Ex. 2004 ¶¶ 84–85. Patent Owner cites evidence demonstrating that these arteries are on the front side of the wrist. PO Resp. 38 (citing Ex. 2010, 44, 71 (Plates 429 and 456)); Ex. 2004 ¶ 85. Patent Owner concludes a POSITA would not have believed Ohsaki's convex surface would benefit Aizawa's device based on this difference in device location on the user's wrist. PO Resp. 38; Ex. 2004 ¶ 85.

Petitioner replies that, despite the differences between Aizawa and Ohsaki identified by Patent Owner, a POSITA would nonetheless have understood from Ohsaki that "a convex surface . . . can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such protrusion." Pet. Reply 15–16 (quoting Ex. 1003 ¶¶ 125–126); Ex. 1047 ¶ 35. According to Petitioner, Ohsaki contrasts between "flat" and "convex" detecting surfaces, and explains the "detected pulse wave is adversely affected by the movement of the user's wrist" with a flat surface but not a convex surface. Pet. Reply 16 (citing Ex. 1014, Figs. 1, 2, 4A–4B, ¶¶ 15, 17, 25); Ex. 1047 ¶ 37. Petitioner asserts "Ohsaki was relied upon not for its exact cover configuration" as Patent Owner suggests, but instead "for the rather obvious concept that a convex surface protruding into a user's skin will prevent slippage." Pet. Reply 18; Ex. 1047 ¶ 37 ("[A]dding a convex surface to Aizawa's flat plate will serve to ***improve*** its tendency to not slip off, not take away from it, since it is well understood

that physically extending into the tissue and displacing the tissue with a protrusion provides an additional adhesive effect.”).

Patent Owner replies “Ohsaki demonstrates that a convex surface alone does ***not*** prevent slipping because Ohsaki’s shape is designed to fit within the underlying bone structure of the wrist and forearm on the backhand side.” Sur-reply 16 (citing Ex. 1014, Figs. 3A–3B, ¶¶ 6, 19, 23–24). Patent Owner asserts “Ohsaki explains that a convex surface on the palm side has a tendency to slip, notwithstanding any alleged ‘physical[] digging.’” *Id.* at 17 (alteration in original). Ohsaki also teaches, according to Patent Owner, “that one should avoid too much pressure because otherwise the user ‘feels uncomfortable,’ which results in movement and a tendency to slip.” *Id.* (citing Ex. 1014 ¶¶ 6, 18, 24).

Upon review of the foregoing arguments and evidence, we conclude a preponderance of the evidence supports Petitioner’s contention that a person of ordinary skill in the art would have been motivated to modify Aizawa’s plate 6 to include a convex protrusion, in order to help prevent slippage of Aizawa’s detector 1 on the user’s wrist, based on Ohsaki.

A person of ordinary skill in the art would have understood from Ohsaki that forming a convex protrusion on the face of an optically-based pulse sensor where it is pressed against the user’s wrist to gather optical data will beneficially prevent slippage of the sensor during operation. Ohsaki states: “The detecting element 2 is arranged on the user’s wrist 4 so that *the convex surface* of the translucent board 8 *is in intimate contact with the surface of the user’s skin. Thereby it is prevented that the detecting element 2 slips* off the detecting position of the user’s wrist 4.” Ex. 1014 ¶ 25 (emphases added). A POSITA would understand from this disclosure that forming a convex protrusion on the tissue-contacting face of a

wrist-worn, optically-based pulse sensor will resist movement of the sensor on the user's wrist during use. *See* Ex. 1003 ¶¶ 141–142; Ex. 1047 ¶ 52. A POSITA would also understand this resistance to be a beneficial result, because it will improve the pulse sensor's ability to emit light into and detect light reflected from the user's wrist, to generate a pulse signal. *See* Ex. 1006 ¶¶ 26, 30, 34; Ex. 1014 ¶¶ 23, 25, 27; Ex. 1003 ¶¶ 125–126; Ex. 1047 ¶ 37.

Indeed, Ohsaki expressly compares the performance of a wrist-worn pulse wave sensor depending on whether translucent board 8 is convex or flat, and concludes the former results in improved performance over the latter, especially when the user is moving. *See* Ex. 1014, Figs. 4A–4B, ¶¶ 15, 25 (stating that with "a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist 4," and with "a convex surface like the present embodiment, the variation of the amount of the reflected light" collected by the sensor "is suppressed"). Ohsaki also states that, with a convex protrusion, it is "prevented that noise such as disturbance light from the outside penetrates the translucent board 8." *Id.* ¶ 25.

Patent Owner and Dr. Madisetti attempt to limit the foregoing disclosures of Ohsaki to its particular context—a sensor having one emitter 6 disposed next to one detector 7 to define a "longitudinal" sensing direction between them, and being attached to the back side rather than the front side of the user's wrist. *See* Ex. 2004 ¶¶ 83–85. We are not persuaded. For example, Ohsaki's disclosure does not support Dr. Madisetti's conclusion that it is *only* in this particular context that a convex protrusion will help prevent slippage. *See* Ex. 1014 ¶ 19 (discussing the longitudinal direction orientation of Ohsaki's sensor); *id.* at Figs. 3A–3B, ¶¶ 16, 23–24 (discussing attaching Ohsaki's sensor to the back side of the wrist). Figures 3A–3B

compare the performance of detecting element 2, including its translucent board 8 having a convex protrusion, and show better performance when it is attached to the back side of the wrist versus the front side of the wrist, when the user is in motion. *See* Ex. 1014 ¶¶ 17 (Fig. 2), 23–24 (Figs. 3A–3B). Because the tested device incorporates a convex protrusion in both instances, Figures 3A–3B do not support Dr. Madisetti's conclusion that "Ohsaki teaches that a protruding surface on the palm side of the wrist would not prevent slipping" — particularly in comparison to a flat surface such as Aizawa's. Ex. 2004 ¶ 85.

We credit, instead, Dr. Kenny's testimony that a person of ordinary skill in the art would have understood from Ohsaki that a convex protrusion will help prevent slippage, even in the context of Aizawa's arrangement of four detectors surrounding a central emitter (or emitters, when modified per Inokawa) attached on the front side of the user's wrist. *See* Ex. 1047 ¶ 37. This is because, even in Aizawa's arrangement, the convex protrusion will "physically extend[] into the tissue and displac[e] the tissue," as is illustrated for example in Ohsaki's Figures 1 and 2, where translucent board 8 physically extends into and displaces the tissue of wrist 4. *Id.*

Dr. Madisetti also testifies that "Aizawa reports that on the palm side of the wrist, a flat surface improves adhesion," so "a POSITA would have believed that adding Ohsaki's protruding surface would have disrupted the improved adhesion properties reported for Aizawa's flat plate." Ex. 2004 ¶ 85 (citing Ex. 1006, Figs. 3A–3B, ¶¶ 13, 26, 28, 30, 34; Ex. 1014, Figs. 3A–3B, ¶¶ 23–24). We disagree with this reading of Aizawa. It is true that Aizawa's plate 6 is illustrated as having a flat surface (Ex. 1006, Fig. 1(b)), and that Aizawa states the plate "improve[s] adhesion" (*id.* ¶ 13). Aizawa also states: "the above belt 7 is fastened such that the acrylic

transparent plate 6 becomes close to the artery 11 of the wrist 10," and "[t]hereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved." *Id.* ¶ 26. These disclosures, however, indicate the improved adhesion is provided by the acrylic material of plate 6, not the flat surface of plate 6 as Dr. Madisetti would have it. *See also id.* ¶¶ 30, 34 ("Since the acrylic transparent plate 6 is provided . . . adhesion between the pulse rate detector 1 and the wrist 10 can be improved . . . ."). Thus, there is no teaching away from using a convex surface to improve the adhesion of Aizawa's detector to the user's wrist. *See, e.g.*, Ex. 1003 ¶ 126; Ex. 1047 ¶ 37.

Finally, we acknowledge that both Aizawa and Ohsaki express a concern about exerting too much pressure against the front side of the user's wrist, because this would make the user uncomfortable. *See, e.g.*, Ex. 1006 ¶¶ 6, 26, 31; Ex. 1014 ¶¶ 6, 18, 24. Thus, a person of ordinary skill in the art would understand that there are operational limits on how large the protrusion can be made in Aizawa. Nonetheless, claim 1 does not place any limitations on the size of the protrusion, and as discussed above a protrusion would improve the ability to avoid slippage of Aizawa's detector 1 when worn on the front side of a user's wrist. Therefore, it would have been obvious to add a protrusion to Aizawa's detector 1 for that purpose, and optimize the size of the protrusion to avoid user discomfort.

Based on the foregoing arguments and evidence, we conclude Petitioner has demonstrated by a preponderance of the evidence that claim 1 is unpatentable as having been obvious over Aizawa, Inokawa, and Ohsaki.

3. Claims 2–9, 11, 13–15, 19–22, and 24–27

Petitioner relies on its arguments from the first ground based on Aizawa and Inokawa in contending that claims 2–9, 11, 13–15, 19–22, and 24–27 are unpatentable under this ground, which adds Ohsaki. *See* Pet. 42; Ex. 1003 ¶ 123–127. In defense of these claims, Patent Owner relies solely on arguments relating to claim 1. *See, e.g.*, PO Resp. 35–39; Ex. 2004 ¶ 86. Thus, for the reasons provided above in relation to the first ground based on Aizawa and Inokawa (all challenged claims) and this ground (claim 1), we conclude Petitioner has demonstrated by a preponderance of the evidence that claims 2–9, 11, 13–15, 19–22, and 24–27 are unpatentable as having been obvious over Aizawa, Inokawa, and Ohsaki.

F. Obviousness over the Combined Teachings of Aizawa, Inokawa, and Mendelson-2006

Petitioner contends that claims 16, 27, and 28 are unpatentable based on Aizawa, Inokawa, and Mendelson-2006. Pet. 43–48. Claim 16 depends from claim 1 and recites, "[t]he noninvasive optical physiological sensing system of claim 1 further comprising a touch-screen display." Ex. 1001, 45:38–39. Claim 27 ultimately depends from claim 19 and further recites, "[t]he noninvasive optical physiological sensing system of claim 26, wherein the noninvasive optical physiological sensing system is comprised as part of a mobile monitoring device." *Id.* at 46:43–46. Claim 28 depends from claim 27 and further recites, "[t]he noninvasive optical physiological sensing system of claim 27, wherein the mobile monitoring device includes a touch-screen display." *Id.* at 46:47–49.

1. Mendelson-2006 (Ex. 1016)

Mendelson-2006 is a journal article titled “A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring,” and discloses a wireless wearable pulse oximeter connected to a personal digital assistant (“PDA”). Ex. 1016, 912.[11]

Figure 1 of Mendelson-2006 is reproduced below.

[11] Petitioner cites to the native page numbers that accompany the article, rather than the page numbers added to Exhibit 1016. *See, e.g.*, Pet. 43–45. We follow Petitioner’s numbering scheme.

Figure 1 illustrates a sensor module attached to the skin (top), and a photograph of a disassembled sensor module and receiver module (bottom). The sensor module includes an optical transducer, a stack of round printed circuit boards, and a coin cell battery. *Id.* at 913.

Figure 2 of Mendelson-2006 is reproduced below.

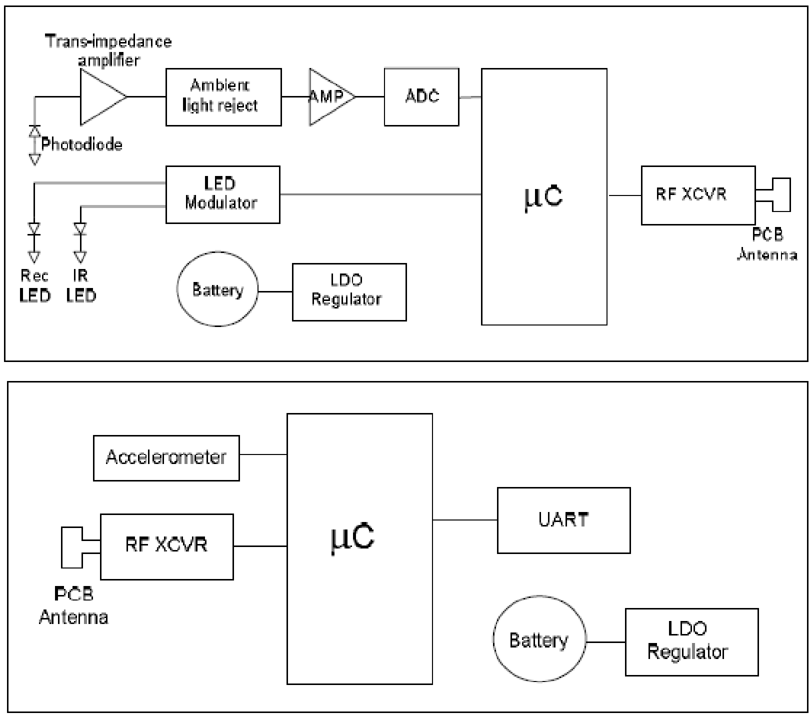


Figure 2 depicts a system block diagram of the wearable, wireless, pulse oximeter including the sensor module (top) and the receiver module (bottom). *Id.* The sensor module includes at least one light-emitting diode ("LED"), a photodetector, signal processing circuitry, an embedded microcontroller, and an RF transceiver. *Id.* at 912, 913. Mendelson-2006 discloses that a concentric array of discrete photodetectors could be used to increase the amount of backscattered light detected by a reflectance type pulse oximeter sensor. *Id.* at 915. The receiver module includes an embedded microcontroller, an RF transceiver for communicating with the

sensor module, and a wireless module for communicating with the PDA. *Id.* at 913.

As a PDA for use with the system, Mendelson-2006 discloses "the HP iPAQ h4150 PDA because it can support both 802.11b and Bluetooth™ wireless communication" and "has sufficient computational resources." *Id.* at 914. Mendelson-2006 further discloses that

> [t]he use of a PDA as a local terminal also provides a low-cost touch screen interface. The user-friendly touch screen of the PDA offers additional flexibility. It enables multiple controls to occupy the same physical space and the controls appear only when needed. Additionally, a touch screen reduces development cost and time, because no external hardware is required. . . . The PDA can also serve to temporarily store vital medical information received from the wearable unit.

Id.

The PDA is shown in Figure 3 of Mendelson-2006, reproduced below.

Figure 3 illustrates a sample PDA and its graphical user interface ("GUI"). *Id.* Mendelson-2006 explains that the GUI allows the user to interact with the wearable system. *Id.* "The GUI was configured to present the input and output information to the user and allows easy activation of various

functions." *Id.* "The GUI also displays the subject's vital signs, activity level, body orientation, and a scrollable PPG waveform that is transmitted by the wearable device." *Id.* For example, the GUI displays numerical oxygen saturation ("SpO_2") and heart rate ("HR") values. *Id.*

2. Analysis

With support from the testimony of Dr. Kenny, Petitioner contends that claims 16, 27, and 28 are unpatentable based on Aizawa, Inokawa, and Mendelson-2006. Pet. 43–48 (citing Ex. 1003 ¶¶ 69–71, 128–136; Ex. 1006 ¶¶ 2, 15, 23, 35; Ex. 1008 ¶ 56; Ex. 1016, 912–914, Figs. 1, 3; Ex. 1022). For instance, Petitioner applies the teachings of Mendelson-2006 to account for the mobile monitoring device features required by claim 27 and the touch-screen display recited in claims 16 and 28. *Id.*

Patent Owner does not separately address this ground urging only that the ground "do[es] not fix the deficiencies" that were alleged in connection with the ground based on Aizawa and Inokawa. PO Resp. 39. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.D.

We have reviewed the parties' papers and supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claims 16, 27, and 28 are unpatentable based on Aizawa, Inokawa, and Mendelson-2006.

G. Obviousness over the Combined Teachings of Aizawa, Inokawa, Mendelson-2006, and Beyer

Petitioner contends that claims 17, 18, and 29 are unpatentable based on Aizawa, Inokawa, Mendelson-2006, and Beyer. Pet. 48–53. Claim 17 depends from claim 1 and recites, "a processor configured to: receive one or

more signals from the at least four detectors, the one or more signals indicative of a physiological parameter of a wearer of the noninvasive optical physiological sensing system; and output information indicative of measurements of the physiological parameter to a mobile phone." Ex. 1001, 45:42–48. Claim 18 depends from claim 17 and further recites, "wherein at least the processor is housed in a mobile monitoring device comprising a touch-screen display." *Id.* at 45:50–51. Claim 29 depends from claim 19 and recites, "[a] physiological monitoring system comprising: the noninvasive optical physiological sensing system of claim 19; and a processor configured to receive the one or more signals and communicate physiological measurement information to a mobile phone." *Id.* at 46:50–55.

1. Overview of Beyer (Ex. 1019)

Beyer is a U.S. patent titled "Cellular Phone/PDA Communication System," and discloses a "cellular PDA communication system for allowing a plurality of cellular phone users to monitor each others' location and status [and] to initiate cellular phone calls." Ex. 1019, code (57). Beyer's Figure 1 is reproduced below.

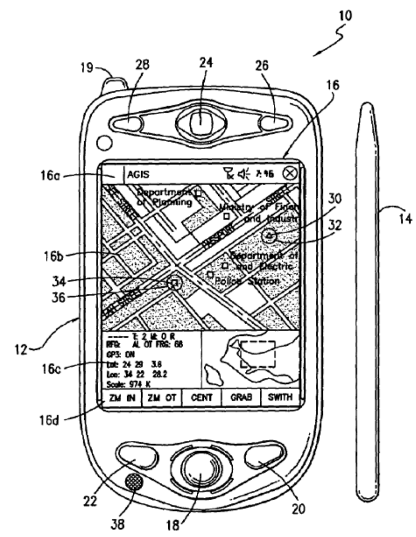


FIG. 1

Figure 1 depicts a "cellular phone/PDA and display." *Id.* at 7:8–9.

2. *Analysis*

With support from the testimony of Dr. Kenny, Petitioner contends that claims 17, 18, and 29 are unpatentable based on Aizawa, Inokawa, Mendelson-2006, and Beyer. Pet. 48–53 (citing, e.g., Ex. 1003 ¶¶ 138–146; Ex. 1016, 913–914; Ex. 1019, 1:6–15, 7:17–31, Fig. 1). For instance, Petitioner applies the teachings of Beyer to account for showing that "using a PDA that is also a mobile phone . . . was common practice," and that such devices can include a touch-screen display, as required by claim 18. *Id.*

Patent Owner does not separately address this ground urging only that the ground "do[es] not fix the deficiencies" that were alleged in connection with the ground based on Aizawa and Inokawa. PO Resp. 39. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.D.

We have reviewed the parties' papers and supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that

claims 17, 18, and 29 are unpatentable based on Aizawa, Inokawa, Mendelson-2006, and Beyer.

H. Obviousness over the Combined Teachings of Aizawa, Inokawa, and Al-Ali

Petitioner contends that claim 10 is unpatentable over Aizawa, Inokawa, and Al-Ali. Pet. 60–62. Dependent claim 10 ultimately depends from independent claim 1 and recites that "the protruding light permeable cover comprises a conductive layer configured to shield the at least four detectors from noise." Ex. 1001, 45:18–20.

1. Overview of Al-Ali (Ex. 1030)

Al-Ali is a U.S. patent application publication titled "Multiple Wavelength Optical Sensor." Ex. 1030, code (54). Al-Ali discloses an optical sensor with an emitter that radiates light into a tissue site to be received by a detector such that, e.g., oxygen saturation may be derived. *Id.* at code (57). Al-Ali describes detector 1900 having shield 1910 with conductive surface 1920 defining windows, shown below in Figure 19A. *Id.* ¶ 71.

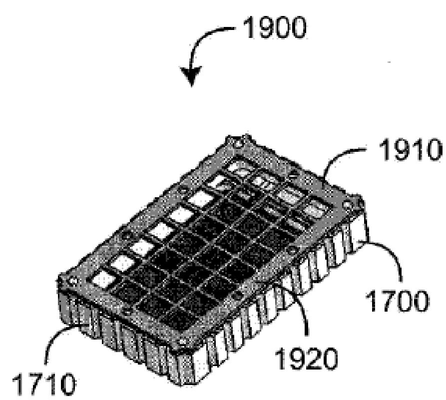


FIG. 19A

Figure 19A depicts a top view of a detector. Al-Ali explains that light is permitted to pass through the windows, while other electromagnetic noise is blocked. *Id*. Al-Ali explains that additional shielding material also can be applied to the ceramic substrate 1710. *Id.*

2. Analysis

Petitioner contends that "Al-Ali teaches shielding the detectors of a pulse oximeter/optical sensor by placing a conductive shield 1920 above the housing, thereby providing a Faraday cage that can allow 'passage of light' to the detectors while 'blocking . . . electromagnetic noise.'" Pet. 60–61 (citing Ex. 1030 ¶ 71, Fig. 19A; Ex. 1003 ¶ 162-A). Petitioner asserts this "improve[s] the sensitivity of the detectors, thereby leading to more reliable pulse/signal detection." *Id.* at 61.

According to Petitioner, a person of ordinary skill in the art "would have found it obvious to add a similar conductive shield/layer between the detectors and the LPC [light permeable cover] to prevent electromagnetic noise from reaching the detectors while still allowing desired signals/wavelengths to pass through, thereby reducing the effects of noise and resulting in improved light collection efficiency." *Id.* (citing Ex. 1003 ¶ 162-B). Petitioner contends that this "entails the use of known solutions to improve similar systems and methods in the same way," and "would have led to [the] predictable result of reducing noise and improving signal collection without significantly altering or hindering the functions performed by Aizawa." *Id.* at 62 (citing Ex. 1003 ¶ 162-C).

Patent Owner does not separately address this ground urging only that the ground "do[es] not fix the deficiencies" that were alleged in connection with the ground based on Aizawa and Inokawa. PO Resp. 39. As discussed

above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.D.

We have reviewed the parties' papers and supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claim 5 is unpatentable based on Aizawa, Inokawa, and Al-Ali. Specifically, Al-Ali teaches the use of a conductive material to eliminate noise. Ex. 1030 ¶ 71. In light of this teaching, we credit Dr. Kenny's unrebutted testimony that a person of ordinary skill in the art would have found it obvious to implement such a conductive material in the sensor of Aizawa and Inokawa to also reduce noise, as was a well-known technique in the art. Ex. 1003 ¶¶ 162-A, 162-B.

I. Obviousness over the Combined Teachings of Aizawa, Inokawa, Goldsmith, and Lo

Petitioner contends that claims 16–18 and 27–29 of the '708 patent are unpatentable over Aizawa, Inokawa, Goldsmith, and Lo. Pet. 53–60.

Because we have already determined that these claims are unpatentable, we need not reach this additional ground applied to these claims. *See Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020); *see supra* §§ II.F–G.

J. Obviousness over the Combined Teachings of Mendelson-1988 and Inokawa

Petitioner contends that claims 1–9, 11–15, and 19–26 of the '708 patent would have been obvious over the combined teachings of Mendelson-

1988 and Inokawa. Pet. 62–90.[12] We note that this is the only ground to challenge claims 12 and 23 of the '708 patent.

1. *Overview of Mendelson-1988 (Ex. 1015)*

Mendelson-1988 discloses a pulse oximeter, with an optical reflectance sensor suitable for noninvasive monitoring of a user's arterial hemoglobin oxygen saturation (SpO_2), via the user's forehead. *See* Ex. 1015, 167 (title & abstract). Figure 2 is reproduced below:

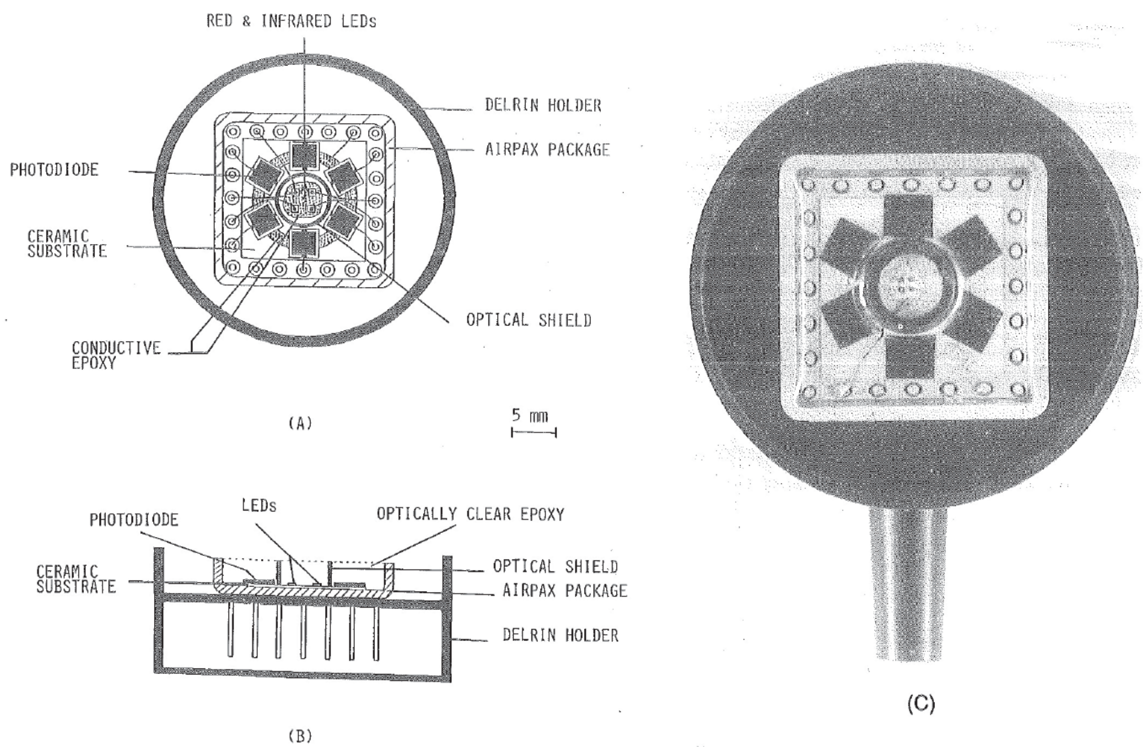


Figure 2 illustrates the sensor of Mendelson-1988, including: (A) a top view diagram; (B) a side view diagram; and (C) a photograph. *Id.* at 169.

[12] Petitioner never refers to the '708 patent in regards to this ground, instead referring to the '190 patent. We assume that this is an oversight and caused by forgetting to change the patent number in reproducing this Petition after drafting the highly similar petition in IPR2021-00195, which challenges the '190 patent. As such, we will assume that Petitioner means to refer to the '708 patent and not the '190 patent.

The sensor includes two red LEDs and two infrared LEDs for emitting light into the user's tissue, and six photodiodes "arranged symmetrically in a hexagonal configuration" surrounding the four emitters, to detect light reflected back to the sensor from the user's tissue. *Id.* at 168 ("SENSOR DESIGN"). The user's "SpO_2 can be calculated from the ratio of the reflected red and infrared photoplethysmograms." *Id.* at 167. "To minimize the amount of light transmission and reflection between the LEDs and the photodiodes within the sensor, a ring-shaped, optically opaque shield of black Delrin . . . was placed between the LEDs and the photodiode chips." *Id.* at 168 (col. 2). "The optical components were encapsulated inside the package using optically clear adhesive." *Id.* "The microelectronic package was mounted inside a black Delrin housing." *Id.*

2. *Independent Claim 1*

i. *"A noninvasive optical physiological sensing system comprising:"*

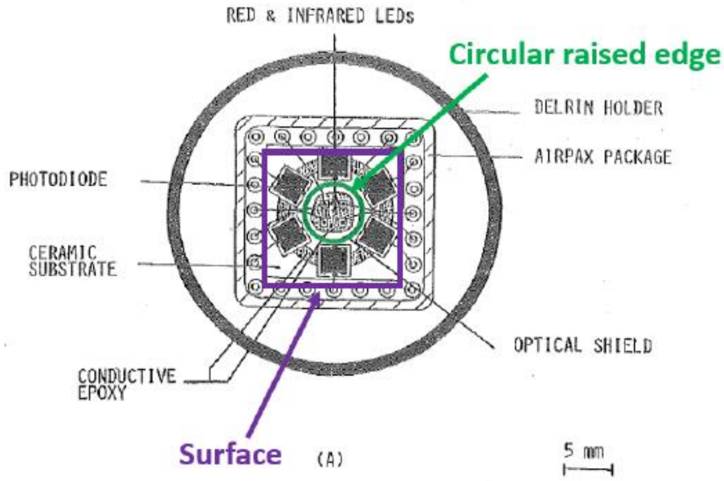
The cited evidence supports Petitioner's undisputed contention that Mendelson-1988 discloses a noninvasive optical physiological measurement system, i.e., an "optical reflectance sensor" that monitors "arterial hemoglobin oxygen saturation [SpO_2]," a physiological parameter of the wearer. Pet. 68; *see, e.g.*, Ex. 1015, 167, 172; Ex. 1003 ¶ 163. Petitioner specifically contends that a person of ordinary skill in the art "would have recognized that a personal computer, together with the pulse oximeter sensor attached to it, provides the claimed sensing system." Pet. 68 (citing Ex. 1003 ¶ 163).

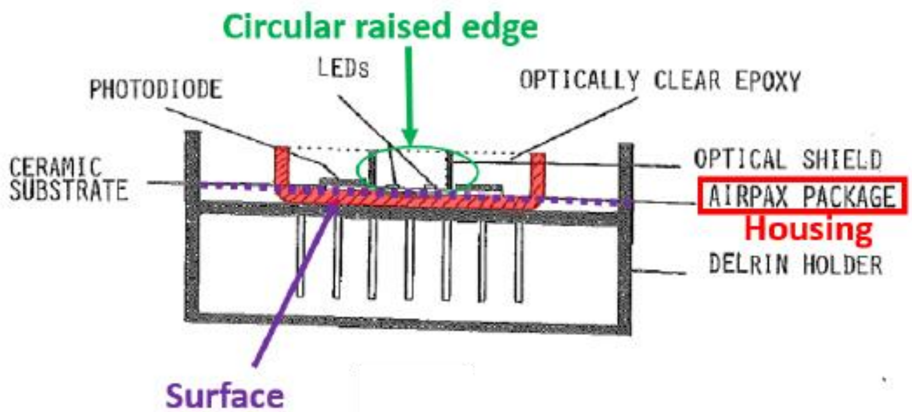
ii. "[a] a platform including a planar surface"

The cited evidence supports Petitioner's undisputed contention that Mendelson-1988 discloses "LEDs and photodiode chips (i.e., emitters and detectors) [that] are mounted on a ceramic substrate (platform) that has a planar surface." Pet. 68 (citing Ex. 1015, Fig. 2(b), 168) (emphasis omitted); *see, e.g.*, Ex. 1003 ¶ 164.

iii. "[b] a housing including a raised edge portion extending from and enclosing at least a portion of the planar surface"

The cited evidence supports Petitioner's undisputed contention that Mendelson-1988 discloses an AIRPAX package, i.e., a housing with a ceramic substrate, i.e., a surface, and a circular raised edge extending from the surface. Pet. 69–70. Petitioner's annotated versions of Mendelson-1988's Figures 2A and 2B are reproduced below.





Id. The modified figures depict top and side views of Mendelson-1988's sensor with a housing (depicted in red) having a surface (depicted in purple) with a circular raised edge (depicted in green) extending from the surface. *Id.*; Ex. 1003 ¶¶ 165–166.

> *iv.* *"[c] at least four detectors arranged on the planar surface of the platform and within the housing, wherein the at least four detectors are arranged in a grid pattern such that a first detector and a second detector are arranged across from each other on opposite sides of a central point along a first axis, and a third detector and a fourth detector are arranged across from each other on opposite sides of the*

central point along a second axis which is perpendicular to the first axis"

The cited evidence supports Petitioner's undisputed contention that Mendelson-1998 discloses "six silicon photodiodes . . . arranged symmetrically in a hexagonal configuration" on the surface. Pet. 70 (citing Ex. 1015, 169, Figs. 2(A)–(B); Ex. 1003 ¶ 167). Petitioner recognizes that Mendelson-1988's "first and second axes as shown above are not perpendicular to each other," but points out that Mendleson-1988 "does not indicate that its system only works with six detectors." Pet. 72 (citing Ex. 1003 ¶ 169; Ex. 1015, 168). According to Petitioner, "a POSITA would have considered using different numbers of spaced-apart detectors, namely 4 or 8, to be obvious and a routine and conventional design choice." *Id.* at 74 (citing Ex. 1006 ¶ 32; Ex. 1003 ¶ 171).

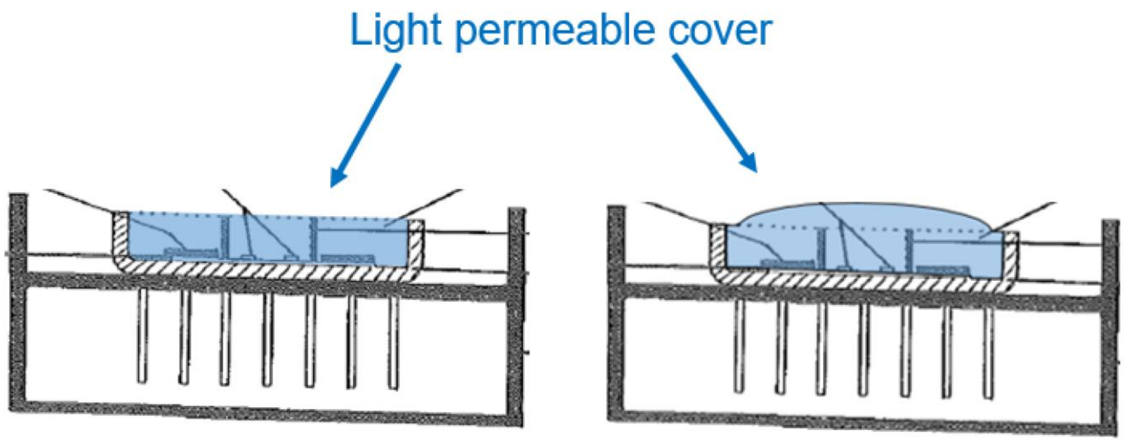
v. "[d] the housing including a protruding light permeable cover"

(1) Petitioner's Contentions

Petitioner contends that Mendelson-1988's sensor discloses all limitations of claim 1, except that its light permeable cover that is arranged above a portion of the housing and covers the detectors, i.e., the "OPTICALLY CLEAR EPOXY" in Figure 2B, lacks the claimed "protrusion." *See* Pet. 64–67, 74–75; Ex. 1003 ¶¶ 172–181. As discussed above in Section II.D.3, Petitioner contends that Inokawa's sensor includes lens 27, comprising a convex protrusion arranged to cover its light detector 25. Pet. 65. Petitioner reasons that an ordinarily skilled artisan would have been motivated, with a reasonable expectation of success, to modify Mendelson-1988's optical SpO_2 sensor, in light of Inokawa's optical

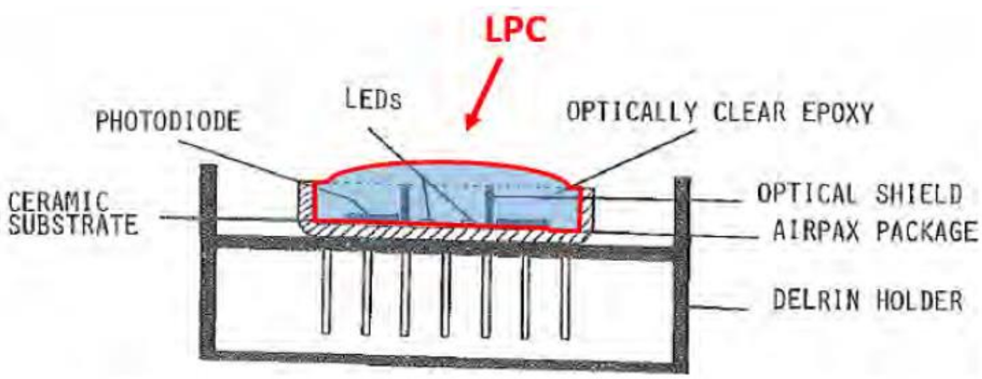
pulse sensor, by adding a lens with a protrusion to Mendelson-1988's cover to improve the sensor's light detection efficiency. *Id.*

Dr. Kenny provides the following illustrations to portray the proposed modification of Mendelson-1988's sensor (Ex. 1003 ¶ 176):

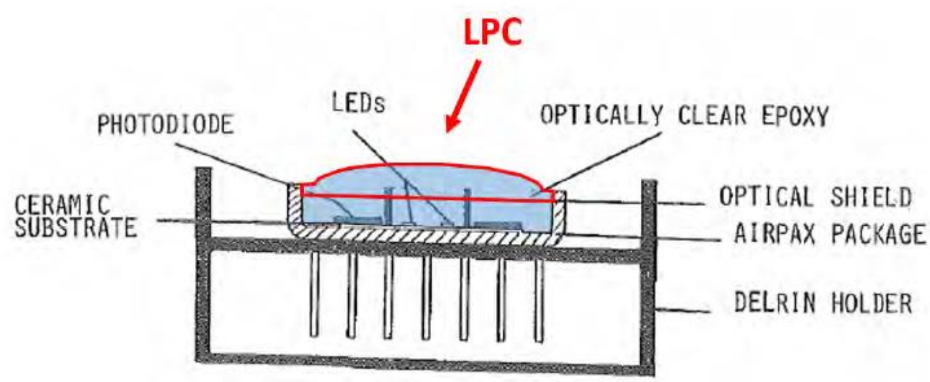


At the left, Dr. Kenny has excerpted and annotated Mendelson-1988's Figure 2B, to identify the pre-existing cover (colored blue) which covers the light emitters and detectors. *See id.* At the right, Dr. Kenny has illustrated the device resulting from the proposed modification of the cover to have a protrusion (also colored blue). *See id.*

Petitioner further asserts "there are two alternative ways of identifying the claimed 'light permeable cover,' or LPC," to the modified cover above. Pet. 74; Ex. 1003 ¶¶ 172–173. Dr. Kenny provides the following two annotations of Mendelson-1988's Figure 2B to identify these alternative mappings:



APPLE-1015, FIG. 2(B)



APPLE-1015, FIG. 2(B).

Dr. Kenny's first mapping (top figure) equates the cover to the entire depth of the epoxy contained within the AIRPAX package as shown in red outline. Ex. 1003 ¶ 180. Dr. Kenny's second mapping (bottom figure) equates the cover to a partial depth of the epoxy within the package as shown in red outline. *Id.* ¶ 181 ("[A person of ordinary skill in the art] would have been able to use the top portion of the housing . . ., as in Nishikawa, to help form the LPC portion on top of the sealing portion.").

Petitioner adds that a person of ordinary skill in the art "would have realized that the epoxy layer [of Mendelson-1998] could have been given a shape that would help further advance Mendelson-1988's objective of improving detection efficiency," "requir[ing] only routine knowledge of

sensor design and assembly." Pet. 64, 66 (citing Ex. 1015, 168, 173); Ex. 1003 ¶¶ 173, 177. For example, "as demonstrated by Nishikawa, molding clear epoxy, as in Mendelson-1988, into a lens was well understood." Pet. 66–67 (citing Ex. 1023, Fig. 6, ¶¶ 22, 32, 35; Ex. 1003 ¶ 178).

(2) Patent Owner's Arguments

Patent Owner is of the view that Petitioner has not met its burden to demonstrate the obviousness of modifying Mendelson-1988's sensor in light of Inokawa to have a protrusion, based on substantially the same analysis and testimony discussed above in the context of combining Aizawa and Inokawa. *See* PO Resp. 39–52; Ex. 2004 ¶¶ 91–115; *supra* Section II.D.3. For example, Mendelson-1988, like Aizawa, provides a central emitter or emitters surrounded by several detectors. *Compare* Ex. 1015, 169 (Fig. 2) (showing four central LEDs surrounded by six photodiodes), *with* Ex. 1006, Figs. 1(a)–1(b) (showing one central LED 21 surrounded by four photodetectors 22).

Patent Owner argues that Mendelson-1988 discloses only that it encapsulates its electronic components with a flat optically clear adhesive/epoxy, which is not a "cover." PO Resp. 45 (citing Ex. 1004 ¶¶ 102–103). Patent Owner contends that the '708 patent distinguishes between resin and covers. PO Resp. 45–46 (citing Ex. 1001, 36:37–46; Ex. 2009, 395:22–396:17). Patent Owner also argues that Nishikawa, on which Petitioner relies, "never mentions a cover, and instead discusses encapsulation of components using an integrally molded resin." *Id.* at 46 (citing Ex. 1023 ¶ 35; Ex. 2004 ¶ 104). Likewise, Patent Owner characterizes Inokawa's cover as a "***distinct structure***, not an

undifferentiated mass of resin on a surface." *Id.* (citing Ex. 1008 ¶ 103, Fig. 17).

Patent Owner also objects to Petitioner's alternative mapping, providing for a cover with a protrusion to be found in two different ways. *See* PO Resp. 46–48; Ex. 2004 ¶¶ 105–107. This alternative mapping, according to Patent Owner, is "ambiguous[]," and the second mapping incorporates an "arbitrary" drawn line defining the bottom of the cover in "an ***undifferentiated*** mass of material." PO Resp. 47. Patent Owner also argues that "Petitioner's inability to consistently identify a 'cover' reveals the hindsight-driven nature of its arguments." *Id.*

(3) Petitioner's Reply

Petitioner maintains that the Petition and supporting testimony adequately account for the "cover" required by the claims of the '708 patent, including the "alternative mapping" configuration. Pet. Reply 19–23.

(4) Patent Owner's Sur-reply

Patent Owner's Sur-reply generally reiterates its arguments challenging Petitioner's contentions. PO Sur-reply 18–23.

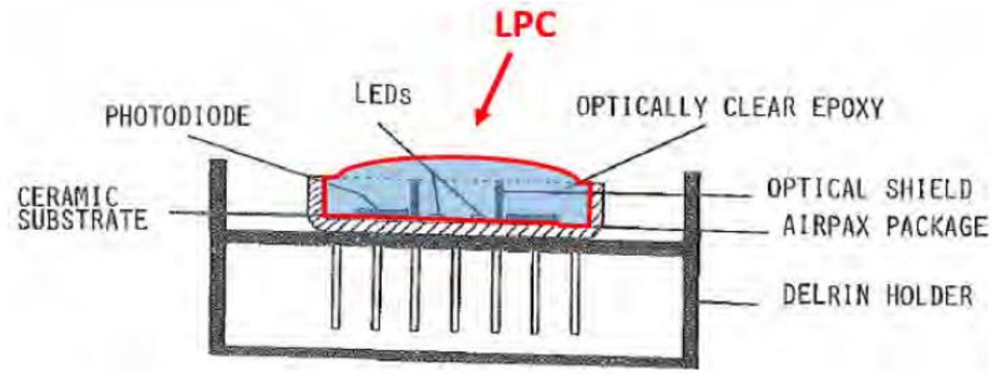
(5) Analysis

As an initial matter, we find that a preponderance of the evidence establishes that the Mendelson-1988 sensor's optically clear epoxy is a light permeable cover that is arranged above a portion of the housing and covers the sensor's detectors. In particular, it is clear from Figures 2A and 2B that the epoxy extends from the top of the sensor at the dotted line in the figure, down into the well of the AIRPAX package, to cover all four LEDs and all six photodiodes disposed at the bottom of the well. *See also* Ex. 1015, 168

("The optical components were encapsulated inside the package using optically clear adhesive"). Although Patent Owner disagrees, that disagreement is premised on its proposed claim construction of the term "cover" as excluding resins and epoxies. *See* PO Resp. 45–48. For reasons provided in Section II.C.1 above, we do not find that claim construction persuasive, and Patent Owner does not distinguish Mendelson-1988 from claim 1 on this basis.

Thus, we determine that Petitioner has established persuasively that Mendelson-1988's sensor teaches every limitation of claim 1, except that its light permeable cover has a flat surface and, thus, does not include a "protrusion." We, however, conclude that a preponderance of the evidence supports Petitioner's contention that it would have been obvious to modify the top surface of Mendelson-1988's cover to include a protrusion, in order to increase the amount of backscattered light that will be received by Mendelson-1988's peripheral detectors. Our reasoning is substantially identical to the analysis provided above in connection with the ground based on Aizawa and Inokawa, with Mendelson-1988 replacing Aizawa in the combination. *See supra* Section II.D.3. Patent Owner does not cite, and we do not discern, any material difference between Mendelson-1988 and Aizawa that might lead to a different result here, with one possible exception.

That difference is Petitioner's alternative mapping of the claimed "cover" to Petitioner's proposed modification of Mendelson-1988's sensor. We rely on the first mapping, but not Petitioner's second mapping, to decide in Petitioner's favor. Petitioner's first mapping is again reproduced here (Ex. 1003 ¶ 180):



APPLE-1015, FIG. 2(B)

In this modified and annotated version of Figure 2B of Mendelson-1988, Dr. Kenny identifies how Mendelson-1988's light permeable cover may be modified to have a protrusion, wherein the cover (which Dr. Kenny has colored blue) includes the entire depth of the optically clear epoxy contained within the AIRPAX package (as Dr. Kenny has shown in red outline). *Id.*; Pet. 74–75. Patent Owner objects to this mapping as ambiguous, but we determine Dr. Kenny's annotations reproduced above are sufficiently clear to establish obviousness by a preponderance of the evidence.

vi. Summary

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 would have been obvious over the cited combination of references.

3. Independent Claim 19

Independent claim 19 consists of limitations that are substantially similar to elements [a]–[d] of claim 1. *Compare* Ex. 1001, 44:36–50, *with id.* at 45:53–46:11 (reciting a "housing including a raised wall protruding"). In asserting that claim 19 also would have been obvious over the combined

teachings of Aizawa and Inokawa, Petitioner refers to substantially the same contentions presented as to claim 1. *See* Pet. 85–88; Ex. 1003 ¶¶ 199–202.

Patent Owner does not present any argument for this claim other than those we have already considered with respect to independent claim 1. PO Resp. 39–48; *see, e.g., id.* at 45 ("Like the Aizawa grounds, Petitioner's Mendelson grounds do not satisfy all of the claim limitations. Claims 1 and 19 include a housing and a light permeable cover.") (citing Ex. 1001, 44:36–50, 45:53–46:11).

For the same reasons discussed above, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 19 would have been obvious over the cited combination of references. *See supra* §§ II.J.2.i–v; Ex. 1003 ¶¶ 172–181.

4. Dependent Claim 3

Claim 3 ultimately depends from claim 1 and recites, "[t]he noninvasive optical physiological sensing system of claim 2, wherein the housing is a cylindrical housing protrusion." Ex. 1001, 44:57–59. Petitioner recognizes that Mendelson-1988's "particular housing shape . . . appears to have a generally rectangular shape, not a cylindrical one." Pet. 77–78 (citing Ex. 1015, Fig. 2(a)). However, Petitioner contends that a person of ordinary skill in the art "would have recognized that microelectronic packaging as used in Mendelson-1988 comes in various shapes and sizes." *Id.* at 78 (citing Ex. 1003 ¶ 185). Petitioner further contends that a person of ordinary skill in the art "would have considered using a differently shaped housing, namely a cylindrical one, to be obvious," and doing so "was common practice" prior to the '708 patent. *Id.* at 78–79 (citing Ex. 1003 ¶ 186).

Petitioner explains that its contentions are evidenced by another reference of record, Mendelson '799.[13] *Id.*

Patent Owner characterizes Petitioner's proposed ground for claim 3 as "facially deficient" for several reasons: (1) "Petition[er] never identifies a motivation to pick a cylindrical-shaped housing instead of the existing square shape"; (2) "[a person of ordinary skill in the art] would have no particular motivation to change the shape unless a [person of ordinary skill in the art] perceived some benefit in doing so"; (3) "Mendelson '799 does not disclose a cover (or even epoxy encapsulation) and thus cannot disclose a cylindrical housing and a cover of the cylindrical housing, as claim 3 requires"; and (4) "Petitioner did not include Mendelson '799 in any ground." PO Resp. 48–49 (citing Ex. 2004 ¶¶ 110–111).

In response to Patent Owner's arguments, Petitioner replies that "references like Mendelson [']799 have a circular housing and confirm the notion that a [person of ordinary skill in the art] would have found it to be simply a matter of design choice to use different shapes." Pet. Reply 23 (citing Ex. 1003 ¶ 186; Ex. 1025, Fig. 7, 9:34–36; Ex. 1047 ¶ 48). Petitioner also contends "neither the '708 patent nor [Patent Owner] provides any explanation of how the particular housing shape solves some problem or presents some unexpected result." *Id.* at 23–24 (citing *In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975)).

Patent Owner responds that "Petitioner's reply reiterates its conclusory arguments that [the proposed] change would be routine, without

[13] U.S. Patent No. 6,801,799 B2, filed Feb. 6, 2003, issued Oct. 5, 2004 ("Mendelson 799," Ex. 1025).

identifying any reason to modify the shape from square to circular." Sur-reply 21–22.

On the record before us, we conclude that a preponderance of the evidence supports Petitioner's contention that it would have been obvious to modify the shape of Mendelson-1988's AIRPAX package from square to circular. Petitioner's and Dr. Kenny's general assessment that a person of ordinary skill in the art would have been aware that a circular housing shape was a known option for housing of components of a physiological sensor finds support in the record. Pet. 77–78; Ex. 1003 ¶ 186. In that respect, although Mendelson '799 was not listed in the styling of the proposed grounds of unpatentability based on Mendelson-1988 and Inokawa, its teachings plainly were offered in the Petition as evidence of the background knowledge that an ordinarily skilled artisan would have brought to bear in an evaluation of the teachings Mendelson-1988 and Inokawa. Pet. 77–78. Moreover, it is clear that Patent Owner understood that the proposed ground offered in the Petition took into account the disclosure of Mendelson '799, and Patent Owner had opportunity to address that disclosure. Indeed, Patent Owner availed itself of that opportunity during trial (*see*, *e.g.*, PO Resp. 48–49; Sur-reply 21–22).

We further find unavailing Patent Owner's argument that "Mendelson '799 does not disclose a cover (or even epoxy encapsulation) and thus cannot disclose a cylindrical housing and a cover of the cylindrical housing, as claim 3 requires." PO Resp. 49. Figure 7 of Mendelson '799 is reproduced below:

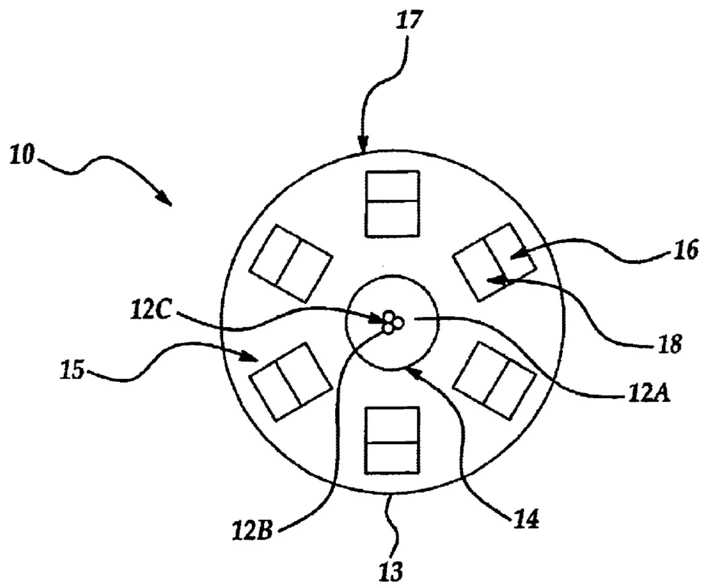


Figure 7

Figure 7 is a top view of optical sensor 10 comprising light source 12 composed of three LEDs 12A, 12B, and 12C emitting light of three different wavelengths, and an array of six near detectors 18 and six far detectors 16 "arranged in two concentric ring-like arrangements" surrounding light source 12. Ex. 1025, 9:23–34. "All these elements are accommodated in a sensor housing 17" which, as can be seen in Figure 7, is clearly circular. *Id.* at 9:34–35. Patent Owner does not articulate why the presence or absence of a cover in Mendelson '799 somehow serves to discount Mendelson '799's unambiguous presentation of a sensor housing having a shape recognizable as circular.

Furthermore, one of ordinary skill in the art would have understood that the AIRPAX package of Mendelson-1988 and the housing 17 of Mendelson '799 are performing the same function of enclosing a central collection of light emitters which are surrounded by an array of light detectors in an optical sensor attached to a user's body. *See, e.g.*, Ex. 1015, Figs. 2A–2B; Ex. 1025, Fig. 7. The evidence of record also does not suggest

that the shape of such a housing has any functional significance in the operation of the optical sensor, or that any particular known shape was preferred or restricted. Thus, the evidence suggests that a square shape and a circular shape of such a housing were known in the art to be predictable substitutes for one another, and therefore obvious variants. *See, e.g.*, *KSR*, 550 U.S. at 416 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result."); *id.* at 417 ("[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." (citation omitted)).

We conclude Petitioner has demonstrated by a preponderance of the evidence that Petitioner's ground based on Mendelson-1988 and Inokawa conveys the unpatentability of claim 3.

5. Dependent Claims 2, 4–9, 11–15, and 20–26

Petitioner provides argument and evidence, including testimony from Dr. Kenny, in support of its position that claims 2, 4–9, 11–15, and 20–26 are unpatentable over Mendelson-1988 and Inokawa. Pet. 76–77, 79–85, 88–90 (citing, e.g., Ex. 1003 ¶¶ 163–209). Patent Owner does not advance any arguments for claims 2, 4–9, 11–15, and 20–26, that are distinct from those provided for claims 1, 3, and 19. *See* PO Resp. 52. For the same reasons set forth in Sections II.J.2–4 above, we find Patent Owner's arguments unavailing as to claims 2, 4–9, 11–15, and 20–26. Having evaluated the Petition and its underlying supporting evidence, we conclude that Petitioner has established by a preponderance of the evidence that

claims 2, 4–9, 11–15, and 20–26 are also unpatentable based on Mendelson-1988 and Inokawa.

K. Obviousness over the Combined Teachings of Mendelson-1988, Inokawa, and Mendelson-2006

Petitioner contends that claims 16, 27, and 28 of the ’708 patent would have been obvious over the combined teachings of Mendelson-1988, Inokawa, and Mendelson-2006. Pet. 90–93.

With support from the testimony of Dr. Kenny, Petitioner contends that claims 16, 27, and 28 are unpatentable based on Mendelson-1988, Inokawa, and Mendelson-2006. Pet. 90–93 (citing Ex. 1003 ¶¶ 129, 210–216; Ex. 1015, 167, 169, Fig. 2; Ex. 1016, 912–915, Figs. 1–3). For instance, Petitioner applies the teachings of Mendelson-2006 to account for the mobile monitoring device features required by claim 27 and the touch-screen display recited in claims 16 and 28. *Id.*

Patent Owner does not separately address this ground urging only that the ground “do[es] not fix the Petition’s deficiencies” that were alleged in connection with the ground based on Mendelson-1988 and Inokawa. PO Resp. 52. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.J.

We have reviewed the Petition and its supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claims 16, 27, and 28 are unpatentable based on Mendelson-1988, Inokawa, and Mendelson-2006.

L. Obviousness over the Combined Teachings of Mendelson-1988, Inokawa, Mendelson-2006, and Beyer

Petitioner contends that claims 17, 18, and 29 of the '708 patent would have been obvious over the combined teachings of Mendelson-1988, Inokawa, Mendelson-2006, and Beyer. Pet. 93–96.

With support from the testimony of Dr. Kenny, Petitioner contends that claims 17, 18, and 29 are unpatentable based on Mendelson-1988, Inokawa, Mendelson-2006, and Beyer. Pet. 93–96 (citing, e.g., Ex. 1003 ¶¶ 72, 217–226; Ex. 1016, 912–915; Ex. 1019, 7:17–31, Fig. 1). The Petition frequently cites back to analysis for previously addressed grounds in explaining the arguments for this ground, as this ground contains many of prior art references and claims that were previously addressed in various capacities within the proposed grounds. *See, e.g.*, *id.* at 94 (analyzing claim 17 and writing "as discussed in Section III.H.1, the combined system of Mendelson-1988-Inokawa-Mendelson-2006 can rely on the receiver module of Mendelson-2006 to receive signals from Mendelson-1988's sensor and communicate with a PDA"). Petitioner further applies the teachings of Beyer to, for example, show that a person of ordinary skill in the art "would have considered using a different PDA than the one mentioned in Mendelson-2006, namely the cellular PDA of Beyer, to be obvious and a routine/conventional design choice," as required by claim 17. *Id.* at 94–95 (citing Ex. 1003 ¶¶ 72, 221–222; Pet. 48–53).

Patent Owner does not separately address this ground urging only that the ground "do[es] not fix the Petition's deficiencies" that were alleged in connection with the ground based on Mendelson-1988 and Inokawa. PO Resp. 52. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.J.

We have reviewed the Petition and its supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claims 17, 18, and 29 are unpatentable based on Mendelson-1988, Inokawa, Mendelson-2006, and Beyer.

III. CONCLUSION

In summary, we determine that a preponderance of the evidence establishes claims 1–29 of the '708 patent are unpatentable, as shown in the following table:[14]

Claim(s)	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–9, 11, 13–15, 19–22, 24–27	103	Aizawa, Inokawa	1–9, 11, 13–15, 19–22, 24–27	
1–9, 11, 13–15, 19–22, 24–27	103	Aizawa, Inokawa, Ohsaki	1–9, 11, 13–15, 19–22, 24–27	
16, 27, 28	103	Aizawa, Inokawa, Mendelson-2006	16, 27, 28	
17, 18, 29	103	Aizawa, Inokawa, Mendelson-2006, Beyer	17, 18, 29	

[14] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

16–18, 27–29	103[15]	Aizawa, Inokawa, Goldsmith, Lo		
10	103	Aizawa, Inokawa, Al-Ali	10	
1–9, 11–15, 19–26	103	Mendelson-1988, Inokawa	1–9, 11–15, 19–26	
16, 27, 28	103	Mendelson-1988, Inokawa, Mendelson-2006	16, 27, 28	
17, 18, 29	103	Mendelson-1988, Inokawa, Mendelson-2006, Beyer	17, 18, 29	
Overall Outcome			1–29	

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1–29 of the ’708 patent have been shown to be unpatentable; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

[15] As explained above, because we conclude that the challenged claims are unpatentable on other grounds, we do not reach the merits of this ground.

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Paper 32
Entered: May 25, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2021-00195
Patent 10,376,190 B1

Before JOSIAH C. COCKS, ROBERT L. KINDER, and AMANDA F. WIEKER, *Administrative Patent Judges.*

WIEKER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

Apple Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–14 and 16–30 ("challenged claims") of U.S. Patent No. 10,376,190 B1 (Ex. 1001, "the '190 patent"). Paper 2 ("Pet."). Masimo Corporation ("Patent Owner") waived filing a preliminary response. Paper 6. We instituted an *inter partes* review of all challenged claims 1–14 and 16–30 on all grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 7 ("Inst. Dec.").

After institution, Patent Owner filed a Response (Paper 15, "PO Resp.") to the Petition, Petitioner filed a Reply (Paper 18, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 22, "PO Sur-reply"). An oral hearing was held on March 15, 2022, and a transcript of the hearing is included in the record. Paper 31 ("Tr.").

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has met its burden of showing, by a preponderance of the evidence, that challenged claims 1–14 and 16–30 of the '190 patent are unpatentable.

B. Related Matters

The parties identify the following matters related to the '190 patent:

Masimo Corporation v. Apple Inc., Civil Action No. 8:20-cv-00048 (C.D. Cal.) (filed Jan. 9, 2020);

Apple Inc. v. Masimo Corporation, IPR2020-01520 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,258,265 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01521 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,292,628 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01523 (PTAB Sept. 9, 2020) (challenging claims of U.S. Patent No. 8,457,703 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01524 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,433,776 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01526 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 6,771,994 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01536 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01537 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01538 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01539 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01713 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,624,564 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01714 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01715 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01716 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,702,194 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01722 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01723 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01733 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,702,195 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01737 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,709,366 B1)

Apple Inc. v. Masimo Corporation, IPR2021-00193 (PTAB Nov. 20, 2020) (challenging claims of U.S. Patent No. 10,299,708 B1);

Apple Inc. v. Masimo Corporation, IPR2021-00208 (PTAB Nov. 20, 2020) (challenging claims of U.S. Patent No. 10,258,266 B1); and

Apple Inc. v. Masimo Corporation, IPR2021-00209 (PTAB Nov. 20, 2020) (challenging claims of U.S. Patent No. 10,376,191 B1).

Pet. 100; Paper 3, 3–4.

Patent Owner further identifies the following pending patent applications, among other issued and abandoned applications, that claim priority to, or share a priority claim with, the ’190 patent:

U.S. Patent Application No. 16/834,538;

U.S. Patent Application No. 17/031,407;

U.S. Patent Application No. 17/031,316;

U.S. Patent Application No. 17/031,356;

U.S. Patent Application No. 16/449,143; and

U.S. Patent Application No. 16/805,605.

Paper 3, 1–3.

C. The ’190 Patent

The ’190 patent is titled “Multi-Stream Data Collection System for Noninvasive Measurement of Blood Constituents,” and issued on August 13,

2019, from U.S. Patent Application No. 16/409,304, filed May 10, 2019. Ex. 1001, codes (21), (22), (45), (54). The ’190 patent claims priority through a series of continuation and continuation-in-part applications to Provisional Application Nos. 61/078,228 and 61/078,207, both filed July 3, 2008. *Id.* at codes (60), (63).

The ’190 patent discloses a two-part data collection system including a noninvasive sensor that communicates with a patient monitor. *Id.* at 2:31–33. The sensor includes a sensor housing, an optical source, and several photodetectors, and is used to measure a blood constituent or analyte, e.g., oxygen or glucose. *Id.* at 2:22–28, 57–58. The patient monitor includes a display and a network interface for communicating with a handheld computing device. *Id.* at 2:38–40.

Figure 1 of the ’190 patent is reproduced below.

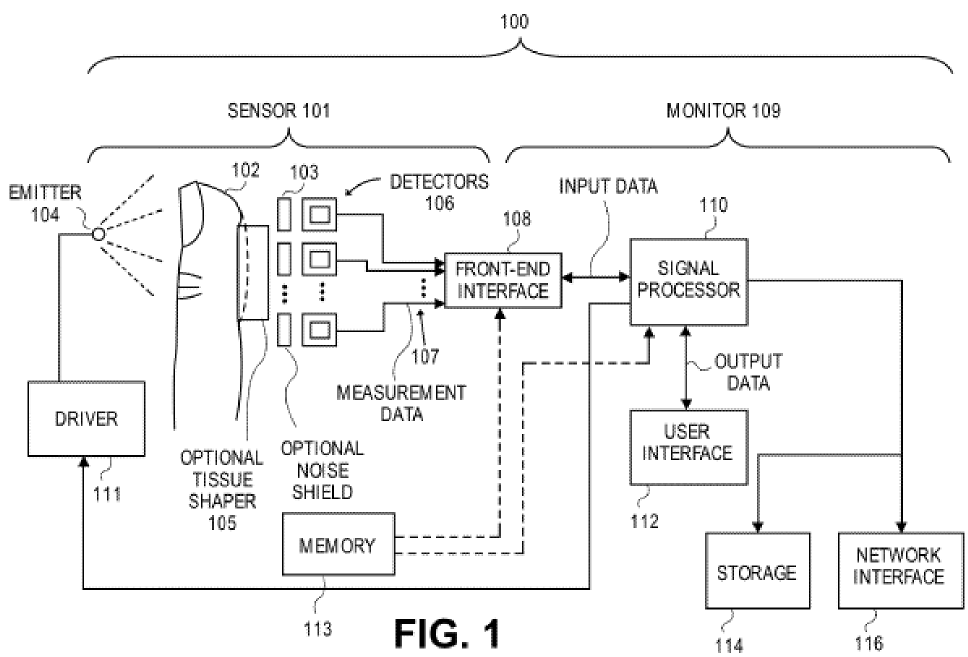

FIG. 1

Figure 1 illustrates a block diagram of data collection system 100 including sensor 101 and monitor 109. *Id.* at 11:36–47. Sensor 101 includes optical emitter 104 and detectors 106. *Id.* at 11:48–52. Emitters 104 emit light that

is attenuated or reflected by the patient's tissue at measurement site 102. *Id.* at 13:60–67. Detectors 106 capture and measure the light attenuated or reflected from the tissue. *Id.* In response to the measured light, detectors 106 output detector signals 107 to monitor 109 through front-end interface 108. *Id.* at 13:64–66, 14:16–22. Sensor 101 also may include tissue shaper 105, which may be in the form of a convex surface that: (1) reduces the thickness of the patient's measurement site; and (2) provides more surface area from which light can be detected. *Id.* at 10:61–11:3.

Monitor 109 includes signal processor 110 and user interface 112. *Id.* at 15:6–8. "[S]ignal processor 110 includes processing logic that determines measurements for desired analytes . . . based on the signals received from the detectors 106." *Id.* at 15:10–14. User interface 112 presents the measurements to a user on a display, e.g., a touch-screen display. *Id.* at 15:38–48. The monitor may be connected to storage device 114 and network interface 116. *Id.* at 15:52–16:3.

The '190 patent describes various examples of sensor devices. Figures 14D and 14F, reproduced below, illustrate detector portions of sensor devices.

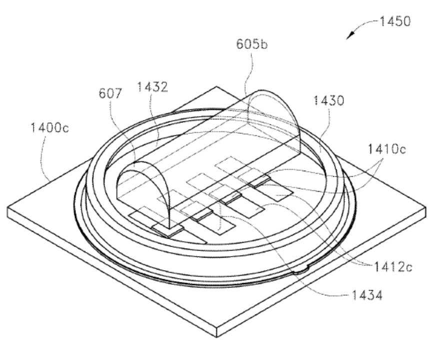

FIG. 14D

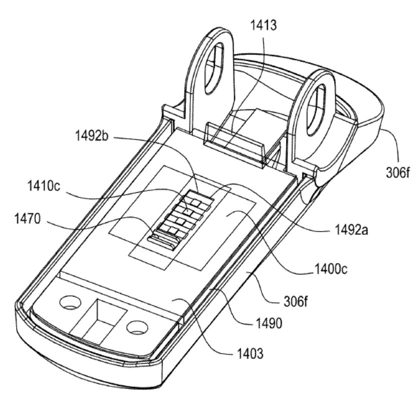

FIG. 14F

Figure 14D illustrates portions of a detector submount and Figure 14F illustrates portions of a detector shell. *Id.* at 6:34–37. As shown in

Figure 14D, multiple detectors 1410c are located within housing 1430 and under transparent cover 1432, on which protrusion 605b (or partially cylindrical protrusion 605) is disposed. *Id.* at 35:23–25, 36:17–24. Figure 14F illustrates detector shell 306f including detectors 1410c on substrate 1400c. *Id.* at 36:63–37:4. Substrate 1400c is enclosed by shielding enclosure 1490 and noise shield 1403, which include window 1492a and window 1492b, respectively, placed above detectors 1410c. *Id.* Alternatively, cylindrical housing 1430 may be disposed under noise shield 1403 and may enclose detectors 1410c. *Id.* at 37:34–36.

Figures 4A and 4B, reproduced below, illustrate an alternative example of a tissue contact area of a sensor device.

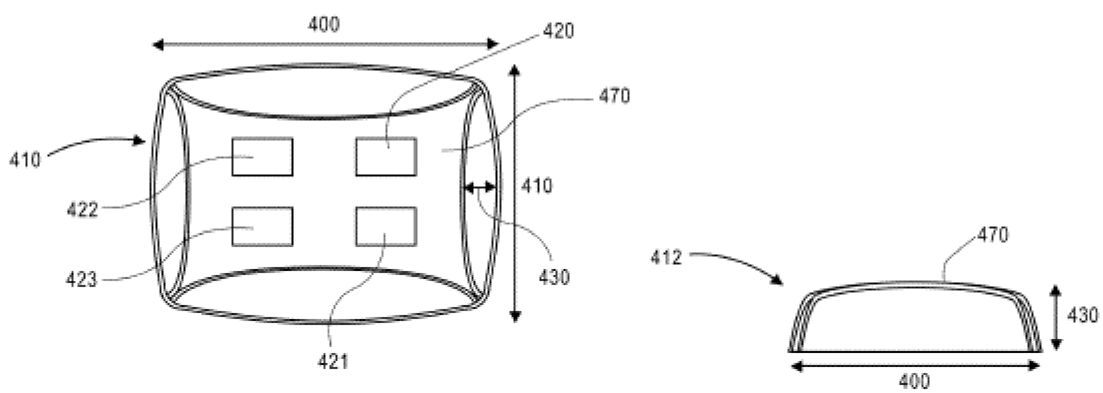

FIG. 4A FIG. 4B

Figures 4A and 4B illustrate arrangements of protrusion 405 including measurement contact area 470. *Id.* at 23:8–14. "[M]easurement site contact area 470 can include a surface that molds body tissue of a measurement site." *Id.* "For example, . . . measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site." *Id.* at 23:31–33. The measurement site contact area may include windows 420–423 that "mimic or approximately mimic a configuration of, or even house, a plurality of detectors." *Id.* at 23:39–53.

D. Illustrative Claim

Of the challenged claims, claims 1 and 26 are independent. Claim 1 is illustrative and is reproduced below.

> 1. A noninvasive optical physiological measurement device adapted to be worn by a wearer, the noninvasive optical physiological measurement device providing an indication of a physiological parameter of the wearer comprising:
>
> [a] one or more light emitters;
>
> [b] a housing having a surface and a circular raised edge extending from the surface;
>
> [c] at least four detectors arranged on the surface and spaced apart from each other, the at least four detectors configured to output one or more signals responsive to light from the one or more light emitters attenuated by body tissue, the one or more signals indicative of a physiological parameter of the wearer; and
>
> [d] a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors.

Ex. 1001, 44:37–53 (bracketed identifiers [a]–[d] added). Independent claim 26 includes limitations substantially similar to limitations [a]–[d] of claim 1. *Id.* at 46:22–40 (reciting a "circular housing" with a "wall"; reciting a "lens portion").

E. Applied References

Petitioner relies upon the following references:

> Beyer, Jr., U.S. Patent No. 7,031,728 B2, filed Sept. 21, 2004, issued Apr. 18, 2006 (Ex. 1019, "Beyer");
>
> Ohsaki et al., U.S. Patent Application Publication No. 2001/0056243 A1, filed May 11, 2001, published December 27, 2001 (Ex. 1014, "Ohsaki");

Aizawa, U.S. Patent Application Publication No. 2002/0188210 A1, filed May 23, 2002, published December 12, 2002 (Ex. 1006, "Aizawa");

Lo et al., U.S. Patent Application Publication No. 2004/0138568 A1, filed Jan. 15, 2003, published July 15, 2004 (Ex. 1028, "Lo");

Inokawa et al., Japanese Patent Application Publication No. 2006-296564 A, filed April 18, 2005, published November 2, 2006 (Ex. 1007, "Inokawa");[1]

Goldsmith et al., U.S. Patent Application Publication No. 2007/0093786 A1, filed July 31, 2006, published April 26, 2007 (Ex. 1027, "Goldsmith");

Al-Ali et al., U.S. Patent Application Publication No. 2008/0242958 A1, filed Mar. 26, 2008, published Oct. 2, 2008 (Ex. 1030, "Al-Ali");

Y. Mendelson et al., "Design and Evaluation of a New Reflectance Pulse Oximeter Sensor," Association for the Advancement of Medical Instrumentation, Vol. 22, No. 4, 167–173 (1988) (Ex. 1015, "Mendelson-1988"); and

Y. Mendelson et al., "A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring," Proceedings of the 28th IEEE EMBS Annual International Conference, 912–915 (2006) (Ex. 1016, "Mendelson-2006").

Pet. 4. Petitioner also submits, *inter alia*, the Declaration of Thomas W. Kenny, Ph.D. (Ex. 1003), and the Second Declaration of Thomas W. Kenny (Ex. 1047). Patent Owner submits, *inter alia*, the Declaration of Vijay K. Madisetti, Ph.D. (Ex. 2004). The parties also provide deposition testimony from Dr. Kenny and Dr. Madisetti, including from this and other proceedings. *See* Exs. 1034–1036, 2006–2009, 2027.

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[1] Petitioner relies on a certified English translation of Inokawa (Ex. 1008). In this Decision, we also refer to the translation.

F. Asserted Grounds

Petitioner asserts that claims 1–14 and 16–30 are unpatentable based upon the following grounds (Pet. 1–2):

Claim(s) Challenged	35 U.S.C. §	References/Basis
1–14, 16, 17, 19–23, 26–29	103	Aizawa, Inokawa
1–14, 16, 17, 19–23, 26–29	103	Aizawa, Inokawa, Ohsaki
23, 24	103	Aizawa, Inokawa, Mendelson-2006
23–25	103	Aizawa, Inokawa, Goldsmith, Lo
25	103	Aizawa, Inokawa, Mendelson-2006, Beyer
5	103	Aizawa, Inokawa, Al-Ali
1–14, 16–22, 26–30	103	Mendelson-1988, Inokawa
23, 24	103	Mendelson-1988, Inokawa, Mendelson-2006
25	103	Mendelson-1988, Inokawa, Mendelson-2006, Beyer

II. DISCUSSION

A. Claim Construction

For petitions filed on or after November 13, 2018, a claim shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b) (2019).

Although both parties contend that no claim term requires express construction (Pet. 4–5; PO Resp. 10), the substance of the parties' briefing demonstrates that there is a dispute regarding the claim term "cover."

1. "cover"

Each of independent claims 1 and 26 requires "a light permeable cover." Ex. 1001, 44:51, 46:33.

Patent Owner argues that the claimed "cover" excludes "an optically clear adhesive/epoxy" and a "resin on a surface." PO Resp. 46–47. According to Patent Owner, "the '190 Patent distinguishes a resin on a surface from a cover, explaining: 'the cylindrical housing 1430 (and transparent cover 1432) . . . can protect the detectors 1410c and conductors 1412c ***more effectively*** than currently-available ***resin epoxies***.'" *Id.* at 47 (quoting Ex. 1001, 36:37–46).

Patent Owner alleges that Dr. Kenny also "distinguished a sealing resin from a cover, acknowledging a 'layer of sealing resin' is 'one way to protect the components ***without using a cover***.'" *Id.* (quoting Ex. 2009, 395:22–396:17). Patent Owner argues its understanding is consistent with the prior art cited by Petitioner. *Id.* (citing Ex. 1008 ¶ 103, Fig. 17; Ex. 1023 ¶ 35; Ex. 1012, 5:2–6, Fig. 2B; Ex. 1013 ¶ 32, Fig. 2; Ex. 1027 ¶ 85, Fig. 9B Ex. 2004 ¶ 104).

Petitioner replies that "there is nothing in the specification or the prosecution history [of the '190 patent] that would lead a [person of ordinary skill in the art] to conclude that 'cover' should be interpreted based on anything other than its plain meaning." Pet. Reply 20 (citing *Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362, 1368 (Fed. Cir. 2012)). That plain meaning, according to Petitioner, is that "a cover is merely 'something that protects, shelters, or guards.'" *Id.* at 20–21 (quoting Ex. 1050; citing Pet. 73–75; Ex. 1047 ¶ 43). Petitioner argues that Patent Owner's reliance on the '190 patent Specification takes text out of context

and, when context is considered, it is clear that "the epoxy resin to which the '190 patent compares its cover is not [an] epoxy cover . . . but rather epoxy that is applied to solder joints." *Id.* at 21 (citing Ex. 1001, 36:37–46; Ex. 1047 ¶ 45).

Petitioner also contends that Patent Owner "mischaracterizes Dr. Kenny's deposition testimony to say he agreed that 'sealing resin' is somehow distinguished from a cover." *Id*. Petitioner contends that Dr. Kenny simply "clarified that using a sealing resin is 'a pretty common way to protect electronic components.'" *Id.* (citing Ex. 2009, 395:22–396:17; Ex. 1047 ¶ 44). Moreover, Petitioner contends that "such extrinsic evidence would not justify departure from plain meaning under *Thorner*." *Id.*

In its Sur-reply, Patent Owner maintains that the '190 patent "specifically ***distinguishes*** a 'resin' on a surface from a 'cover,'" and Petitioner's opposing reading is not persuasive. PO Sur-reply 18–19.

Upon review of the record, we disagree with Patent Owner's limiting construction of "cover" to exclude epoxy and resin. The plain and ordinary meaning of the term does not support Patent Owner's view. A "cover" ordinarily connotes "something that protects, shelters, or guards." Ex. 1050 (*Merriam-Webster's Collegiate Dictionary*, 11th ed. (©2005)), 288. That plain and ordinary meaning is consistent with the '190 patent's description of "flex circuit cover 360, which can be made of plastic or another suitable material . . . [and] can cover and thereby protect a flex circuit (not shown)." Ex. 1001, 22:62–66. It is also consistent with the '190 patent's description and illustration of "transparent cover 1432" in Figure 14D, which covers and protects detectors 1410c and conductors 1412c, and which "can be

fabricated from glass or plastic, *among other materials*." *See id.* at 36:22–36 (emphasis added), Figs. 14D–14E.

This is not the situation in which a special definition for a claim term has been set forth in the specification with reasonable clarity, deliberateness, and precision, so as to give notice of the inventor's own lexicography. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005); *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Nor do we discern that Patent Owner "demonstrate[d] an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002).

Here, based upon our review of the intrinsic evidence, no such special definition or express disavowal of the term "cover" to exclude epoxy and resin exists. Patent Owner relies on the following description of Figure 14D in that regard:

> *In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432)* forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, *in certain embodiments, the cylindrical housing 1430 can protect* the detectors 1410c and conductors 1412c *more effectively than currently-available resin epoxies*, which are sometimes applied to solder joints between conductors and detectors.

Ex. 1001, 36:37–46 (emphases added). First, the sentence cited by Patent Owner begins with the phrase "[i]n certain embodiments," which indicates the claimed invention is not limited and is open to other embodiments, so there is no lexicography or disavowal here. Second, we agree with

Petitioner's reading of this passage as distinguishing the prior art from the claimed invention based on the *location* of the material (applied only to solder joints between conductors and detectors in the prior art, as opposed to covering the conductors and detectors in the invention) and not the *type* of material. Third, at best, the '190 patent expresses a preference for a cover to be made of glass or plastic, because such materials provide "more effective[]" protection than resin epoxies that were known when the '190 patent was filed. *See id.* at 36:42–46. But even this reading recognizes that resin epoxies provide some amount of protection, albeit perhaps a lesser amount than glass or plastic, and are not excluded from forming the material of a cover.

Dr. Kenny's deposition testimony cited by Patent Owner also does not persuade us that, in the context of the '190 patent, epoxy or resin is excluded from the material of a cover. Dr. Kenny testifies that "a layer of sealing resin" "[c]ould" be used to protect the electronic components in a sensor (Ex. 2009, 395:22–396:8). He was then asked "So that would be one way to protect the components without using a cover, correct?" to which he answered "[t]here are many ways to protect the elements other than using a cover" and maintained that the proposed combination of prior art has a "cover" to achieve purposes *other than* protecting electronic components, i.e., "to improve adhesion and to improve light gathering for the operation of the system." *Id.* at 396:9–17. He did not squarely testify that sealing resin may never be a cover.

Accordingly, in the context of the '190 patent, we do not construe the claimed "cover" to exclude epoxy and resin.

2. Other Claim Terms

Upon consideration of the entirety of the arguments and evidence presented, we conclude no further explicit construction of any claim term is needed to resolve the issues presented by the arguments and evidence of record. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (claim terms need to be construed "only to the extent necessary to resolve the controversy" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of non-obviousness.[2] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art

[2] Patent Owner does not present objective evidence of non-obviousness.

elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner identifies the appropriate level of skill in the art as that possessed by a person having "a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information." Pet. 5 (citing Ex. 1003 ¶¶ 21–22). "Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline." *Id.*

Patent Owner makes several observations regarding Petitioner's identified level of skill in the art but, "[f]or this proceeding, [Patent Owner] nonetheless applies Petitioner's asserted level of skill." PO Resp. 10–11 (citing Ex. 2004 ¶¶ 35–38).

We adopt Petitioner's assessment as set forth above, which appears consistent with the level of skill reflected in the Specification and prior art.

D. Obviousness over the Combined Teachings of Aizawa and Inokawa

Petitioner contends that claims 1–14, 16, 17, 19–23, and 26–29 of the ’190 patent would have been obvious over the combined teachings of Aizawa and Inokawa. Pet. 8–42.

1. Overview of Aizawa (Ex. 1006)

Aizawa is a U.S. patent application publication titled “Pulse Wave Sensor and Pulse Rate Detector,” and discloses a pulse wave sensor that detects light output from a light emitting diode and reflected from a patient’s artery. Ex. 1006, codes (54), (57).

Figure 1(a) of Aizawa is reproduced below.

FIG. 1 (a)

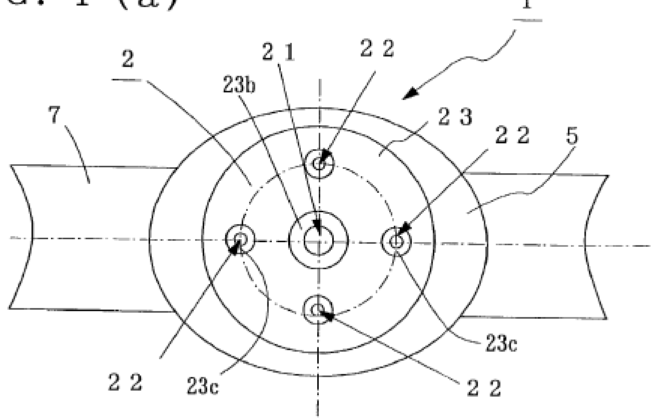


Figure 1(a) is a plan view of a pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(a), pulse wave sensor 2 includes light emitting diode (“LED”) 21, four photodetectors 22 symmetrically disposed around LED 21, and holder 23 for storing LED 21 and photodetectors 22. *Id.* Aizawa discloses that, “to further improve detection efficiency, . . . the number of the photodetectors 22 may be increased.” *Id.* ¶ 32, Fig. 4(a). “The same effect can be obtained when the number of photodetectors 22 is [one] and a

plurality of light emitting diodes 21 are disposed around the photodetector 22." *Id.* ¶ 33.

Figure 1(b) of Aizawa is reproduced below.

FIG. 1 (b)

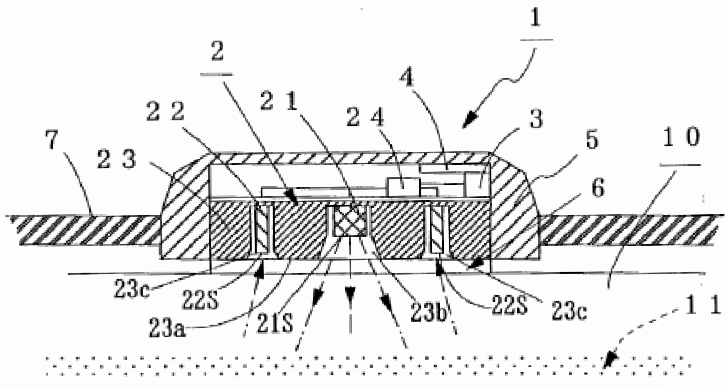


Figure 1(b) is a sectional view of the pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(b), pulse wave sensor 2 includes drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of photodetectors 22. *Id.* ¶ 23. Arithmetic circuit 3 computes a pulse rate from the detected pulse wave and transmitter 4 transmits the pulse rate data to an "unshown display." *Id.* The pulse rate detector further includes outer casing 5 for storing pulse wave sensor 2, acrylic transparent plate 6 mounted to detection face 23a of holder 23, and attachment belt 7. *Id.* ¶ 23.

Aizawa discloses that LED 21 and photodetectors 22 "are stored in cavities 23b and 23c formed in the detection face 23a" of the pulse wave sensor. *Id.* ¶ 24. Detection face 23a "is a contact side between the holder 23 and a wrist 10, respectively, at positions where the light emitting face 21s of the light emitting diode 21 and the light receiving faces 22s of the photodetectors 22 are set back from the above detection face 23a." *Id.* ¶ 24. Aizawa discloses that "a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 . . . in such a manner that the light emitting

face 21s of the light emitting diode 21 faces down (on the wrist 10 side)." *Id.* ¶ 26. Furthermore, "the above belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10. Thereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved." *Id.* ¶¶ 26, 34.

2. Overview of Inokawa (Ex. 1008)

Inokawa is a Japanese published patent application titled "Optical Vital Sensor, Base Device, Vital Sign Information Gathering System, and Sensor Communication Method," and discloses a pulse sensor device. Ex. 1008 ¶ 6.

Figure 1 of Inokawa is reproduced below.

(FIG. 1)

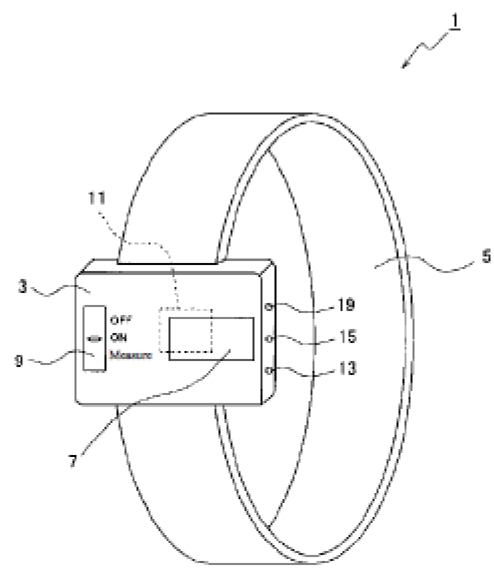


Figure 1 illustrates a schematic view of a pulse sensor. *Id.* ¶ 56. Pulse sensor 1 includes box-shaped sensor unit 3 and flexible annular wristband 5. *Id.* ¶ 57. Sensor unit 3 includes a top surface with display 7 and control switch 9, and a rear surface (sensor-side) with optical device component 11 for optically sensing a user's pulse. *Id.*

Figure 2 of Inokawa is reproduced below.

(FIG. 2)

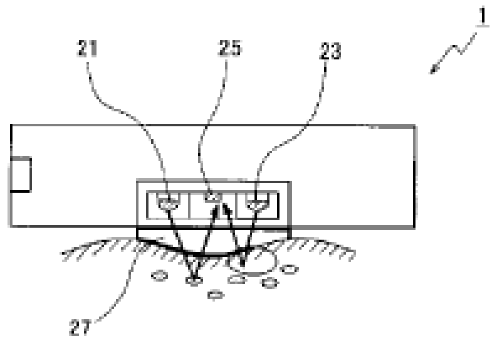


Figure 2 illustrates a schematic view of the rear surface of the pulse sensor. *Id.* ¶ 58. The rear-side (sensor-side) of pulse sensor 1 includes a pair of light-emitting elements, i.e., green LED 21 and infrared LED 23, as well as photodiode 25 and lens 27. *Id.* In various embodiments, Inokawa discloses that the sensor-side lens is convex. *See id.* ¶¶ 99, 107. Green LED 21 senses "the pulse from the light reflected off of the body (i.e.[,] change in the amount of hemoglobin in the capillary artery)," and infrared LED 23 senses body motion from the change in reflected light. *Id.* ¶ 59. The pulse sensor stores this information in memory. *Id.* ¶ 68. To read and store information, the pulse sensor includes a CPU that "performs the processing to sense pulse, body motion, etc. from the signal . . . and temporarily stores the analysis data in the memory 63." *Id.* ¶ 69.

Figure 3 of Inokawa is reproduced below.

(FIG. 3)

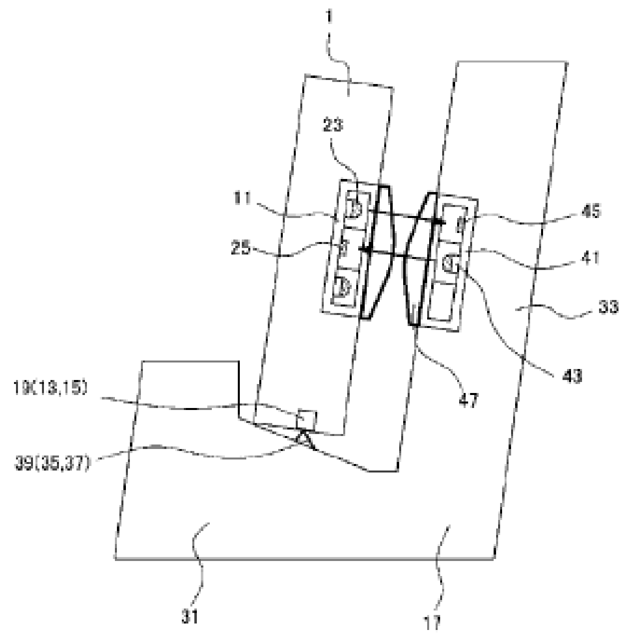


Figure 3 illustrates a schematic view of a pulse sensor mounted to a base device. *Id.* ¶ 60. Pulse sensor 1 is depicted as mounted to base device 17, which "is a charger with communication functionality." *Id.* When so mounted, sensor optical device component 11 and base optical device component 41 face each other in close proximity. *Id.* ¶ 66. In this position, pulse sensor 1 can output information to the base device through the coupled optical device components. *Id.* ¶ 67. Specifically, the pulse sensor CPU performs the controls necessary to transmit pulse information using infrared LED 23 to photodetector 45 of base device 17. *Id.* ¶¶ 67, 70, 76. In an alternative embodiment, additional sensor LEDs and base photodetectors can be used to efficiently transmit data and improve accuracy. *Id.* ¶ 111.

3. Independent Claim 1

Petitioner contends that claim 1 would have been obvious over the combined teachings of Aizawa and Inokawa. Pet. 13–17 (combination), 17–23 (claim 1).

i. "A noninvasive optical physiological measurement device adapted to be worn by a wearer, the noninvasive optical physiological measurement device providing an indication of a physiological parameter of the wearer comprising"

The cited evidence supports Petitioner's undisputed contention that Aizawa discloses a noninvasive optical physiological measurement device, i.e., a pulse sensor worn on a wearer's wrist, that indicates a physiological parameter of the wearer. Pet. 17; *see, e.g.*, Ex. 1006 ¶ 2 ("[A] pulse wave sensor for detecting the pulse wave of a subject from light reflected from a red corpuscle in the artery of a wrist of the subject by irradiating the artery of the wrist with light.").

ii. "[a] one or more light emitters"

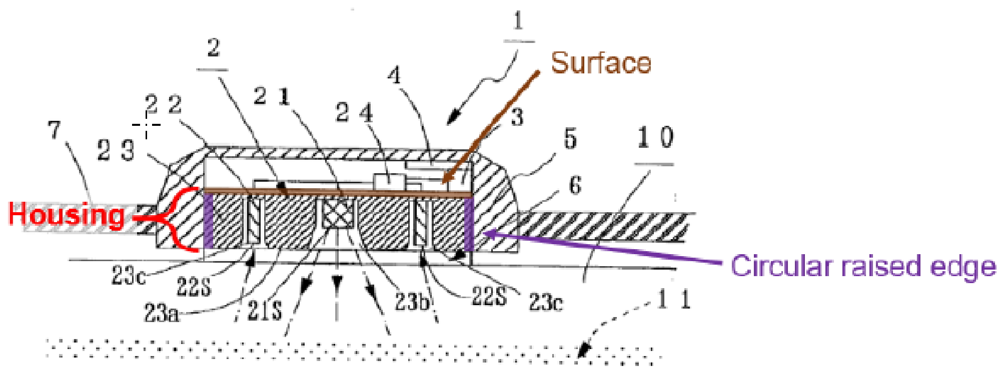
The cited evidence supports Petitioner's undisputed contention that Aizawa discloses LED 21 that emits light. Pet. 17–18; *see, e.g.*, Ex. 1006 ¶ 23 ("LED 21 . . . for emitting light having a wavelength of a near infrared range"), Figs. 1(a)–(b).

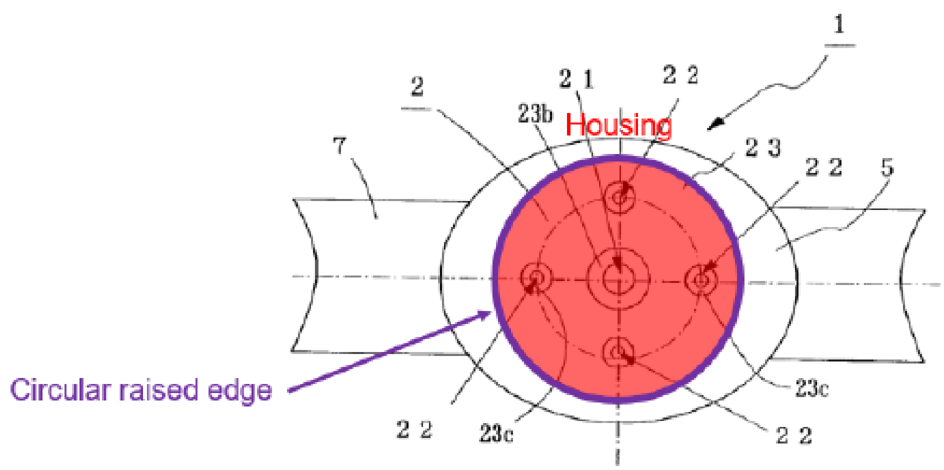
iii. "[b] a housing having a surface and a circular raised edge extending from the surface"

The cited evidence supports Petitioner's undisputed contention that Aizawa discloses holder 23, which includes a flat surface and a circular raised edge extending from the surface. Pet. 18–19; *see, e.g.*, Ex. 1006 ¶ 23

(“holder 23 for storing . . . light emitting diode 21 and the photodetectors 22”), Figs. 1(a)–(b) (depicting holder 23 surrounding each detector 22); Ex. 1003 ¶¶ 75–76.

Petitioner’s annotated versions of Aizawa’s Figures 1(a) and 1(b) are reproduced below.





Pet. 18–19. The modified figures depict side and top views of Aizawa’s sensor with the housing identified in red shading, the circular raised edge identified in purple, and the surface depicted in brown. *Id.*

> *iv.* *"[c] at least four detectors arranged on the surface and spaced apart from each other, the at least four detectors configured to output one or more signals responsive to light from the one or more light emitters attenuated by body tissue, the one or more signals indicative of a physiological parameter of the wearer"*

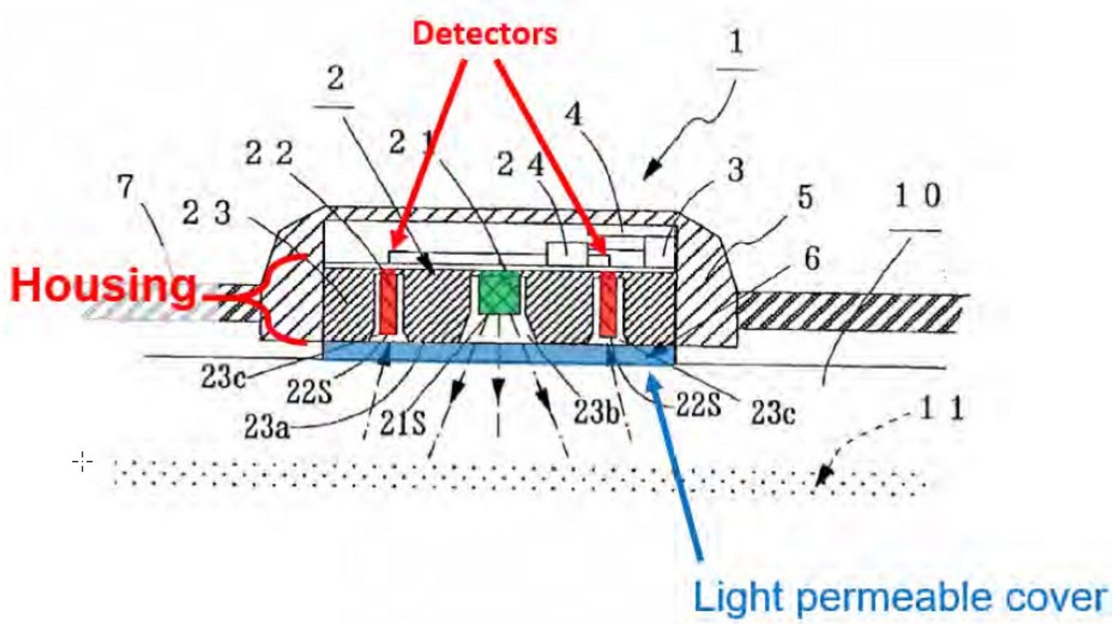
The cited evidence supports Petitioner's undisputed contention that Aizawa discloses at least four detectors 22 that are spaced apart on the surface, wherein the detectors output one or more signals indicative of a physiological parameter of the wearer, e.g., pulse, in response to light emitted by LED 21 that is attenuated by body tissue. Pet. 19–21; *see, e.g.*, Ex. 1006, Fig. 1(a) (depicting detectors 22 spaced apart around LED 21), ¶¶ 23 ("drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of the photodetectors 22"), 27 ("Near infrared radiation output toward the wrist 10 from the light emitting diode 21 is reflected by a red corpuscle running through the artery 11 of the wrist 10 and this reflected light is detected by the plurality of photodetectors 22 so as to detect a pulse wave."), 28 ("[T]he amplified output is converted into a digital signal for the computation of a pulse rate."); Ex. 1003 ¶¶ 77–79.

> *v.* *"[d] a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors."*

<u>Petitioner's Contentions</u>

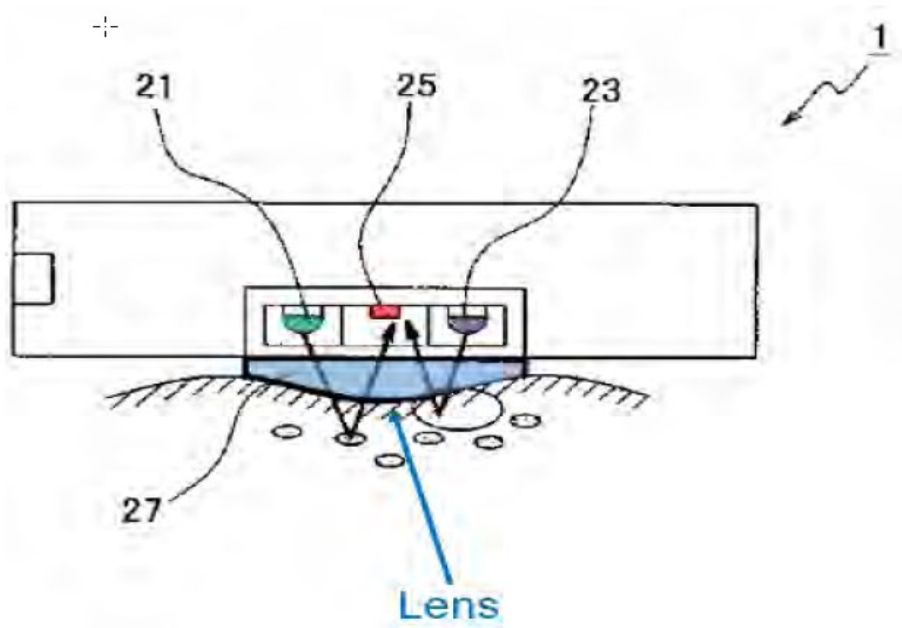
With reference to an annotated version of Aizawa's Figure 1(b) (reproduced below), Petitioner contends that "Aizawa teaches a light permeable cover in the form of an acrylic transparent plate 6 (blue) that is

mounted at the detection face 23a over at least a portion of the housing to cover the at least four detectors (red)." Pet. 22.



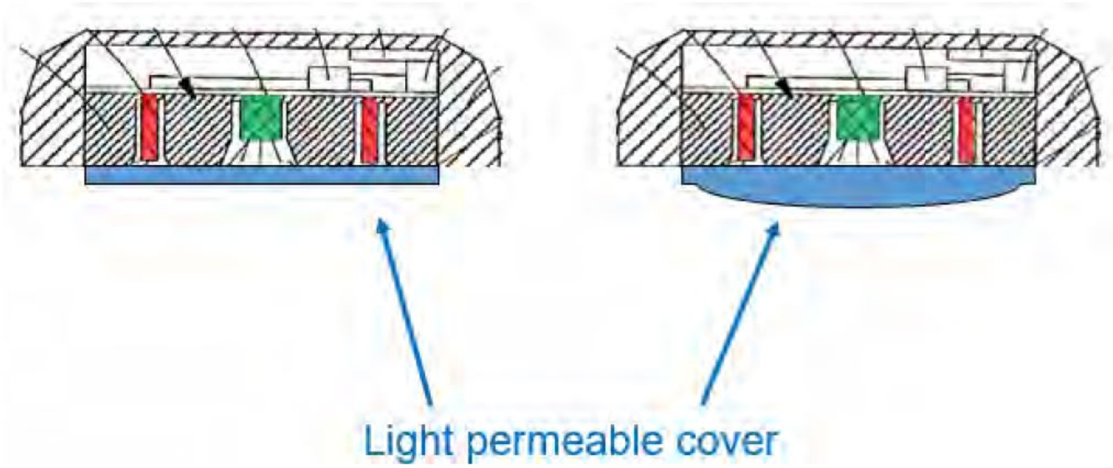
The figure above shows Petitioner's annotated version of Aizawa's Figure 1(b), in which transparent plate 6 is shaded in blue and identified as "Light permeable cover." Petitioner contends that beyond disclosing that the acrylic transparent "helps [to] improve 'detection efficiency,' Aizawa does not provide much other detail, for instance regarding its shape." *Id.* at 13 (citing Ex. 1006 ¶ 30).

Petitioner reasons, however, that one of ordinary skill in the art would have "looked to Inokawa to enhance light collection efficiency, specifically by modifying the light permeable cover of Aizawa to include a convex protrusion that acts as a lens." *Id.* at 14. In that regard, Petitioner points to Inokawa's Figure 2. Petitioner's annotated version of that figure is reproduced below.



Id. Figure 2 above depicts Inokawa's lens 27 shaded in blue. Petitioner expresses that "Inokawa teaches that its cover may be either flat . . . such that 'the surface is less prone to scratches'" or may be in the form of the lens shape shown above to "increase the light-gathering ability of the LED." *Id.* at 15 (quoting Ex. 1008 ¶ 15); *see* Ex. 1003 ¶¶ 83–87. Petitioner contends that a person of ordinary skill in the art "making the design choice to prioritize improved light collection efficiency over reduced suseptibility to scratches could have readily modified Aizawa's cover to include a lens as per Inokawa." Pet. 16 (citing Ex. 1003 ¶ 99). Petitioner also contends that a skilled artisan would have had a reasonable expectation of success in combining those teachings. *Id.* at 15 (citing Ex. 1003 ¶ 86). Petitioner adds that Aizawa's "transparent acrylic material . . . can be readily formed into a lens structure as in Inokawa." *Id.* at 16 (citing Ex. 1003 ¶ 87; Ex. 1009, 3:46–51, Fig. 1; Ex. 1023, Fig. 6, ¶¶ 22, 32, 35).

Petitioner provides annotated and modified versions of Aizawa's Figure 1(b) that depict the proposed combination, which are reproduced below. *Id.* at 15 (citing Ex. 1003 ¶ 85).



Petitioner's annotated figure on the left depicts Aizawa's device with its flat cover, and the annotated and modified figure on the right depicts the device resulting from the combination of Aizawa and Inokawa, in which a person of ordinary skill in the art would have replaced Aizawa's flat cover with a cover comprising a protrusion to "increase the light-gathering ability." *Id.* (quoting Ex. 1008 ¶ 15).

According to Petitioner, a person of ordinary skill in the art "would have understood how to implement Inokawa's lens in Aizawa's device with a reasonable expectation of success." Pet. 15–16 (citing Ex. 1008, Figs. 16, 17, ¶¶ 15, 106); Ex. 1003 ¶ 86. The shape of the modified cover in Dr. Kenny's illustration of the proposed modification above is similar to the shape of an LED lens illustrated in Exhibit 1023 (hereafter "Nishikawa"),[3] referenced by Petitioner and Dr. Kenny in connection with the proposed

[3] U.S. Patent Application Publication No. 2007/0145255 A1, filed Dec. 20, 2006, published June 28, 2007 (Ex. 1023).

ground of unpatentability. *Compare* Pet. 15 (illustrating proposed modification), *with* Ex. 1023, Fig. 6, ¶¶ 3, 22, 30, 32, 35 (illustrating lens 50 used with LED 22, and discussing how to make the illustrated device).

Patent Owner's Arguments

Patent Owner contends that the evidence does not support Petitioner's contention that it would have been obvious to modify Aizawa's cover to have a convex protrusion, in order to improve detection efficiency by directing incoming light to Aizawa's photodetectors 22, with a reasonable expectation of success. PO Resp. 12–37; PO Sur-reply 1–13; Ex. 2004 ¶¶ 48–78.

According to Patent Owner, the evidence establishes that Petitioner's proposed modification would direct light *toward the center* of Aizawa's detector 1 where emitter 21 is located, rather than *toward the periphery* where detectors 22 are located. PO Resp. 16–24; Ex. 2004 ¶¶ 50–65. Thus, Patent Owner's view is that a person of ordinary skill in the art "would ***not*** have expected Inokawa's protruding surface to accomplish" the objective of enhancing light collection efficiency relied upon by Petitioner, because Petitioner's proposed modification instead "would direct light ***away*** from the ***periphery***-located detectors" in Aizawa, the opposite result to Petitioner's contention. PO Resp. 20; Ex. 2004 ¶¶ 42–43, 48–57.

In support, Patent Owner points to Inokawa's Figure 2, in which two arrows illustrate light that passes through the convex protrusion of lens 27 toward the center of Inokawa's pulse sensor 1 where detector 25 is located. PO Resp. 14 (citing Ex. 1008 ¶ 58), 18; Ex. 2004 ¶¶ 42–43. Patent Owner also points to the '190 patent's Figure 14B, which illustrates several light rays 1420, 1422 passing through a partially cylindrical protrusion 605 to be

centrally focused on detector(s) 1410B. PO Resp. 19 (citing Ex. 1001, 35:67–36:2, 36:56–60; Ex. 2004 ¶¶ 53–55). Patent Owner cites portions of Dr. Kenny's deposition testimony that, in Patent Owner's view, support Patent Owner's contentions in these regards. *See* PO Resp. 2, 17–18 (citing Ex. 2006, 83:15–84:2, 86:19–87:1, 202:11–204:20).

Patent Owner also asserts that "Dr. Kenny admitted that the impact of Inokawa's convex lens would not be 'obvious' in the context of [the] different configuration of LEDs and detectors" presented by Aizawa. PO Resp. 20–21 (citing Ex. 2006, 87:2–6). For example, Patent Owner points out that "light reaching Aizawa's detectors must travel in an opposite direction from the light in Inokawa." *Id.* at 21–22 (citing Ex. 1006, Fig. 1(b); Ex. 1008, Fig. 2); Ex. 2004 ¶¶ 61–64. In addition, according to Patent Owner, "Petitioner's combination is particularly problematic because" Aizawa uses "small detectors [22] with small openings [of cavities 23c] surrounded by a ***large*** amount of ***opaque*** material." PO Resp. 22 (citing Ex. 1006, Fig. 1(a)); Ex. 2004 ¶ 63. In support of its view, Patent Owner cites portions of Dr. Kenny's deposition testimony. *See* PO Resp. 22 (citing Ex. 2006, 257:11–18).

Patent Owner further argues that Dr. Kenny, during his deposition, attempted to evade the foregoing problems by "disclaim[ing] Petitioner's reasoning [for obviousness] and assert[ing] new and improper opinions" that undermine the reasoning provided in the Petition. PO Resp. 24. For example, Patent Owner asserts that Dr. Kenny's attempt to distinguish between the '190 patent's Figure 14B as illustrating a lens that condenses *collimated* light toward the center, as compared to Aizawa and Inokawa in which the lens focuses *diffuse* light reflected by the user's body is not

persuasive and is not supported by record evidence. PO Resp. 25–26 (citing Ex. 2006, 170:9–171:5; Ex. 2007, 288:13–289:5, 294:17–298:10, 298:11–299:18, 423:7–424:18); Ex. 2004 ¶¶ 67–68. Patent Owner also objects to Dr. Kenny's testimony that, "while a protruding surface would generally direct more light to the center," it "would also capture some light that otherwise would not be captured" by Aizawa's detectors 22, as lacking evidentiary support and relying on impermissible hindsight. PO Resp. 26–27 (citing Ex. 1001, 7:61–63; Ex. 2004 ¶¶ 69–70; Ex. 2006, 204:21–206:5, 206:22–208:1; Ex. 2007, 294:17–298:10).

Patent Owner moreover asserts that "Dr. Kenny repeatedly distanced himself from his own similar combination" of Aizawa and Inokawa by refusing to talk about the specific shape, size, material, and dimensional tolerances of the combination, so, in Patent Owner's view, his testimony falls short because it demonstrates at most only that the references could have been combined. *Id.* at 2–3, 27–31 (citing, e.g., Ex. 2004 ¶¶ 71–73; Ex. 2006, 51:14–52:16, 75:20–77:2, 91:9–92:13, 96:20–21, 97:11–21, 100:17–101:18, 132:10–18, 154:4–7, 164:8–16, 189:11–190:3; Ex. 2007, 308:12–309:8, 310:18–311:9, 318:3–6, 324:21–325:19, 333:20–335:4).

Indeed, according to Patent Owner, because ordinary skill does not require specific education or experience with optics or optical physiological monitors (*see supra* Section II.C), "[i]t strains credibility that a [person of ordinary skill in the art] . . . could balance all of the factors Dr. Kenny identified" to reach the claimed invention. PO Resp. 32. Patent Owner relies on Dr. Kenny's testimony as establishing the complexity of designing optical physiological sensors. *Id.* at 3–4, 32–33 (citing Ex. 2006, 86:19–87:6; Ex. 2007, 331:19–332:11, 336:11–337:15). Patent Owner concludes

Petitioner has failed to establish a reasonable expectation of success because Dr. Kenny's testimony "focuses almost entirely on manufacturing." *Id.* at 33 (citing Ex. 1003 ¶ 87; Ex. 2004 ¶ 75).

Patent Owner moreover asserts Petitioner errs in relying on Nishikawa as supporting the unpatentability of claim 1, because Nishikawa is "not identified as part of" the ground, which instead "includes only two references," Aizawa and Inokawa. PO Resp. 34 (citing Pet. 1, 13–14; Ex. 1003 ¶¶ 82–87); *id.* at 35–36 (citing 35 U.S.C. § 312(a)(3); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016)). Patent Owner asserts Dr. Kenny "relies heavily" on Nishikawa, particularly "to inform the specific shape of the cover in his combination, which is found nowhere in Aizawa and Inokawa." *Id.* at 34–35 (citing Pet. 23; Ex. 2004 ¶¶ 76–77; Ex. 2006, 179:21–180:13; Ex. 2007, 364:2–13; Ex. 2008, 73:8–12).

Furthermore, in Patent Owner's view, Dr. Kenny's reliance on Nishikawa "make[s] no sense" because "Nishikawa's device is not a physiological sensor" but rather is "an encapsulated LED" that "directs ***outgoing*** light through the encapsulation material and thus focuses on the emission of light, not the detection of an optical signal." PO Resp. 36 (citing Ex. 1023, code (57), ¶¶ 3, 32, 35; Ex. 2004 ¶ 78). Patent Owner contrasts such disclosure with Aizawa and Inokawa, both of which "detect[] ***incoming*** light that passes through the cover and reaches the detectors," and which have a "drastically" smaller scale than Nishikawa's LEDs. *Id.* (citing Ex. 1008, Fig. 2; Ex. 2004 ¶ 78).

Petitioner's Reply

In reply, Petitioner insists "Inokawa's lens enhances the light-gathering ability of Aizawa," which would have motivated an ordinarily skilled artisan "to incorporate 'an Inokawa-like lens [having a protrusion] into the cover of Aizawa to increase the light collection efficiency.'" Pet. Reply 2–3 (bolding omitted) (citing Pet. 13–15; Ex. 1003 ¶¶ 80–87; Ex. 1008, Fig. 2, ¶¶ 15, 58). Petitioner dismisses Patent Owner's and Dr. Madisetti's opposition as being "misinformed" because a person of ordinary skill in the art "would understand that Inokawa's lens generally improves 'light concentration at pretty much all of the locations under the curvature of the lens,' as opposed to only at a single point at the center." *Id.* at 3–4 (quoting Ex. 2006, 164:8–16); Ex. 1047 ¶¶ 7–9.

For example, Petitioner contends that Patent Owner and Dr. Madisetti "ignore[] the well-known principle of reversibility," by which "a ray going from P to S will trace the same route as one from S to P." Pet. Reply 4 (underlining omitted) (citing, e.g., Ex. 1052,[4] 84, 87–92); Ex. 1047 ¶¶ 10–22. Petitioner contends that Dr. Madisetti was evasive when he was asked to apply the reversibility principle to the combination of Aizawa and Inokawa in this case. Pet. Reply 6 (citing Ex. 1034, 89:12–19, 84:2–85:7). Petitioner further contends that, "based at least on the principle of reversibility," one of ordinary skill in the art "would have understood that both configurations of LEDs and detectors—i.e., with the LED at the center as in Aizawa or with

[4] Eugene Hecht, *Optics* (2nd ed. 1990). In referring to Exhibit 1052, Petitioner refers to the document's native page numbering (top corner of each page) and not the added page numbering of the exhibit (bottom, middle of each page). For consistency, we also refer to the native page numbering of Exhibit 1052.

the detector at the center as in Inokawa—would similarly benefit from the enhanced light-gathering ability of an Inokawa-like lens." *Id.* at 9 (citing Ex. 1047 ¶ 22).

Petitioner also asserts that Patent Owner and Dr. Madisetti overlook the fact that light rays reflected by body tissue in the user's wrist, to be received by detectors in either Aizawa's or Inokawa's pulse sensor, will be "scattered" and "diffuse" and, therefore, will approach the detectors "from various random directions and angles." Pet. Reply 9–10, 13 (annotating Inokawa's Fig. 2 to illustrate the cause and nature of the back-scattering); Ex. 1047 ¶¶ 23–26. This scattered and diffuse light, according to Petitioner, means that Inokawa's "lens cannot focus all light toward the sensor's center," as Patent Owner would have it. Pet. Reply 9 (citing Ex. 1047 ¶ 23; Ex. 2006, 163:12–164:2). Petitioner asserts this is due to Snell's law, and provides several illustrations to illustrate why. *Id.* at 9–15 (citing, e.g., Ex. 1047 ¶¶ 23–34).

Due to the random nature of this scattered light, Petitioner explains that one of ordinary skill in the art would have understood that a convex cover "provides a slight refracting effect, such that light rays that may have missed the detection area are instead directed toward that area." Pet. Reply 10 (citing Ex. 1047 ¶¶ 25–26). Petitioner applies this understanding to Aizawa, and contends that using a lens with a convex protrusion in Aizawa would "enable backscattered light to be detected within a circular active detection area surrounding" a central light source. *Id.*

Moreover, Petitioner dismisses the applicability of Figure 14B of the '190 patent as illustrating the operation of a *transmittance*-type of sensor that measures the attenuation of collimated light transmitted through the

user's body tissue, rather than the *reflectance*-type sensor of Aizawa. *Id.* at 11–13 (citing, e.g., Ex. 1001, 35:65–67; Ex. 1047 ¶¶ 27–31).

Petitioner further maintains that illustrations of the light-focusing properties of a convex lens discussed in the Petition filed in IPR2020-01520 (Ex. 2019, 39) and relied upon by Dr. Kenny (Ex. 2020, 119–120) do not demonstrate "that a convex lens directs all light to the center." Pet. Reply 15 (citing PO Resp. 16–18, 23). Petitioner contends these illustrations, instead, "are merely simplified diagrams included to illustrate . . . one example scenario (based on just one ray and one corpuscle) where a light permeable cover can 'reduce a mean path length of light traveling to the at least four detectors'" as recited in claim 12 of the patent challenged in that proceeding. *Id.* (citing, e.g., Ex. 1047 ¶ 34).

Patent Owner's Sur-reply

Patent Owner asserts that Petitioner's Reply improperly presents several new arguments, relying on new evidence, as compared with the Petition. *See, e.g.*, PO Sur-reply 1 ("new optics theories" and "new arguments"), 2, 6, 7, 9, 10, 12, 13.

Patent Owner also contends that Petitioner mischaracterizes Patent Owner's position, which is not that Inokawa's lens with a convex protrusion "would direct '***all***' light 'only at a ***single point*** at the center'" of the sensor. *Id.* at 2, n.2 (quoting Pet. Reply 3; citing, e.g., Ex. 2027, 63:7–64:6, 94:20–96:1, 96:18–97:7). Patent Owner's position, rather, is that Inokawa's lens condenses more light (not necessarily all light) "***towards the center*** of the sensor" as compared to a flat surface. *Id.* at 2 (quoting PO Resp. 19; citing, e.g., Ex. 2004 ¶¶ 34, 43, 49, 51–52, 54–55, 67).

Patent Owner moreover asserts "[t]here can be no legitimate dispute that a convex surface directs light centrally (and away from the periphery)." PO Sur-reply 3–6 (citing PO Resp. 15–18; Ex. 2006, 164:8–16, 166:10–17, 170:22–171:5; Ex. 2020 ¶¶ 119, 200; Ex. 2027, 181:9–182:5). Patent Owner contends that Petitioner's argument "that Inokawa would improve light-gathering at all locations, ***regardless*** of the location of the LEDs and detectors" is belied by Dr. Kenny's testimony that "Inokawa's benefit would ***not*** be clear if Inokawa's LEDs and detectors were moved" and "confirmed that a convex surface would direct light toward the center of the underlying sensor." *Id.* at 6 (citing Pet. Reply 3–4; Ex. 2006, 86:19–87:6, 202:11–204:20).

Patent Owner argues that Petitioner's discussion of the principle of reversibility is "irrelevant" because it "assumes ideal conditions that are not present when tissue scatters and absorbs light." PO Sur-reply 6–8 (citing Ex. 2027, 17:12–19:2, 29:11–30:7, 31:8–32:3, 38:17–42:6, 207:9–209:21, 210:8–6). The random nature of backscattered light, in Patent Owner's view, "hardly supports Petitioner's argument that light will necessarily travel the same paths regardless of whether the LEDs and detectors are reversed," and is irrelevant to the central issue presented here of "whether a convex surface—***as compared with a flat surface***—would collect and focus additional light on Aizawa's peripherally located detectors." *Id.* at 8–9 (citing Ex. 2027, 212:3–14).

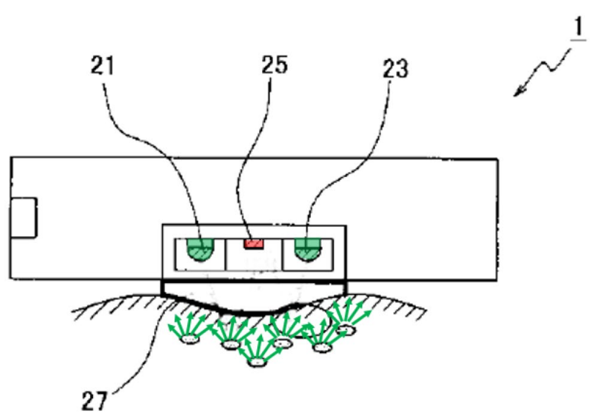
Patent Owner also argues that Petitioner's position that a convex cover will provide a "***slight***" refracting effect, "directly undermines Petitioner's provided ***motivation*** to combine," i.e., to enhance light collection efficiency. *Id.* at 10–11.

Analysis

Upon review of the foregoing, we conclude that a preponderance of the evidence supports Petitioner's view that it would have been obvious to modify Aizawa's cover 6 to include a convex lens or protrusion like that taught in Inokawa, in order to increase the amount of backscattered light that will be received by Aizawa's four peripheral detectors 22, as compared with Aizawa's existing flat cover.

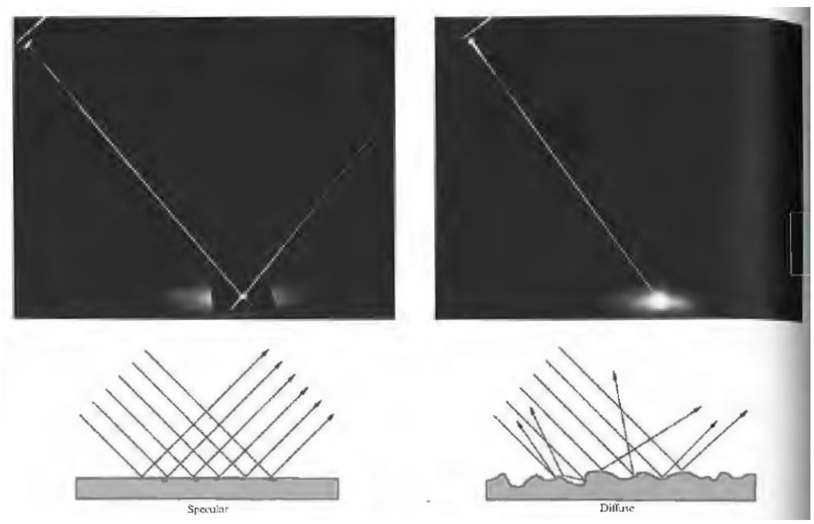
Aizawa's and Inokawa's pulse sensors both gather data by emitting light into the user's wrist tissue and collecting the light that reflects back to the sensor from the user's tissue. *See, e.g.*, Ex. 1006, Figs. 1(b), 2 (sensor 2 has emitter 21 and four detectors 22, all facing a user's wrist 10); Ex. 1008, Figs. 1, 2 (sensor 1 has two emitters 21, 23 and one detector (photodiode 25), all facing the user's wrist when held in place by wristband 5). Dr. Kenny testifies, and Patent Owner agrees, that the reflection of this light by the user's wrist tissue randomizes the propagation direction of the reflected light rays. *See* Ex. 1003 ¶ 117; Ex. 1047 ¶¶ 14–15; Ex. 2020 ¶ 128; PO Sur-reply 7–8 ("Even Petitioner admits that tissue randomly scatters and absorbs light rays.").

This reflection principle is illustrated by Dr. Kenny's annotations to Inokawa's Figure 2 reproduced below:



Here, Dr. Kenny has modified Inokawa's Figure 2 by (1) removing two black arrows, (2) coloring Inokawa's light detector in red and Inokawa's two light emitters in green, and (3) adding several green arrows to illustrate the various directions that light rays may be directed after impinging on and reflecting off different tissues in the user's wrist. Ex. 1047 ¶ 32.

This randomized direction of reflected light rays results in backscattered light that is diffuse, rather than collimated, in nature. Figure 4.12 of Exhibit 1052 illustrates the difference between diffuse and collimated light, and is reproduced below:

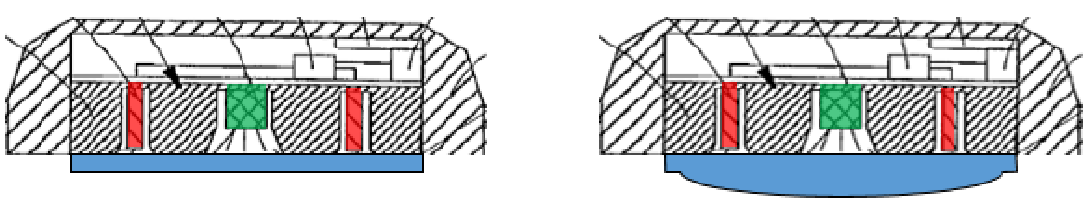


This figure provides at left a photograph and an illustration showing incoming collimated light reflecting from a smooth surface, and at right a photograph and an illustration of incoming collimated light reflecting from a rough surface. *See* Ex. 1052, 87–88. The smooth surface provides specular reflection, in which the reflected light rays are collimated like the incoming light rays. *See id.* By contrast, the rough surface provides diffuse reflection, in which the reflected light rays travel in random directions. *See id.*

This diffuse nature of the light reflected from the user's wrist tissue, which both Aizawa and Inokawa aim to collect to generate pulse data,

suggests that a lens might be useful to increase the amount of collected light and thereby increase the reliability of the pulse data generated using the collected light. Indeed, that is taught by Inokawa. Inokawa describes using its lens 27 to "increase the light-gathering ability" of Inokawa's light photodiode or detector 25.[5] Ex. 1008 ¶¶ 15, 58. Furthermore, there is also no dispute that Inokawa's lens 27 is understood to be shaped as a convex protrusion. *See, e.g.*, Ex. 1003 ¶¶ 83–84 (characterizing Inokawa as teachings a "convex protrusion that acts as a lens"); PO Resp. 1 (describing Inokawa as teaching a "convex lens"). Thus, Inokawa demonstrates that it was known in the art to use a lens comprising a protrusion to focus diffuse light reflected from body tissue on to the light detecting elements of a wrist-worn pulse sensor, and to increase the light gathered by the sensor thereby improving the device's calculation of the user's pulse.

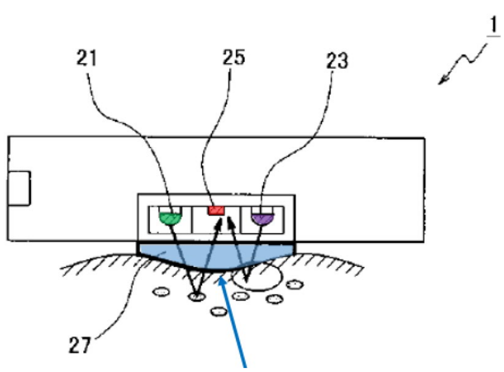
A preponderance of the evidence supports Petitioner's view that it would have been obvious for a person of ordinary skill in the art to apply Inokawa's lens technology to Aizawa's wrist-worn pulse sensor, to similarly improve its light collection as compared to Aizawa's existing flat cover. That is depicted in the following illustrations provided by Dr. Kenny:

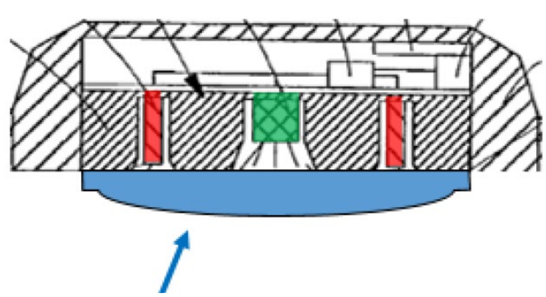


[5] Although Inokawa refers to the "LED" such as emitters 21, 23 in that regard (Ex. 1008 ¶ 15), rather than photodiode 25, it is undisputed that photodiode 25 is the only component of Inokawa's sensor 1 that gathers light.

The illustration at left modifies Aizawa's Figure 1(b) to color Aizawa's emitter in green, its detectors in red, and Aizawa's existing flat cover in blue; the illustration on the right includes Aizawa's Figure 1(b) with the same coloring, but wherein the flat cover is modified to incorporate a convex protrusion that covers Aizawa's peripheral light detectors and central light emitter. *See* Ex. 1003 ¶ 85. We are persuaded by Dr. Kenny's testimony that Snell's law indicates that "light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover," and is especially true "in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source." Ex. 1049 ¶ 26; *see also id.* ¶¶ 23–26.

Patent Owner correctly notes that Inokawa's single detector 25 is located in the central portion of Inokawa's sensor 1, whereas Aizawa's four detectors 22 are located towards the periphery of Aizawa's sensor 2. *Compare* Ex. 1008, Fig. 2, *with* Ex. 1006, Figs. 1(a)–1(b). Nevertheless, Petitioner's proposed modification of Aizawa takes that arrangement into account, as can be seen by the following comparison between Inokawa's sensor and Petitioner's proposed modification of Aizawa's sensor:





The illustration at left annotates Inokawa's Figure 2 to identify the central detector in red and the lens in blue (*see* Ex. 1003 ¶ 83), and the illustration at right annotates Petitioner's proposed modification of Aizawa to illustrate the peripheral detectors in red and the lens in blue (*see id.* ¶ 85). As can be seen, the lenses are not identical. In Inokawa the lens's curvature is most pronounced at the center of the lens near the central detector, and in the proposed modification to Aizawa, the lens's curvature is most pronounced at the edges of the lens near the peripheral detectors. Thus, Dr. Kenny's proposed modification of Aizawa takes Inokawa's general teaching of using a convex protruding lens to increase the amount of incoming light directed to a light detector, and applies it to the four light detectors of Aizawa. *See, e.g.*, Ex. 1003 ¶ 85 ("POSITA would have found it obvious to make the protrusion portion of the LPC [light permeable cover]—namely the lens-shaped light-gathering portion—to ensure that the light-concentration effect achieved by the lens impacts all of the detectors."); *id.* ¶¶ 84–87; Ex. 1047 ¶¶ 7–34.

We are cognizant of Patent Owner's contention that Petitioner's ground "improperly" relies upon a reference, Nishikawa, that was not identified as a part of the ground of unpatentability. PO Resp. 34. As Patent Owner observes, Dr. Kenny characterizes his testimony as being "***inspired*** by" or "motivated" in part based on Nishikawa's disclosure when it comes to the shape of a convex lens. *See, e.g.*, PO Resp. 35–37 (citing, e.g., Ex. 2007, 364:2–13; Ex. 2008, 73:8–12). We, however, disagree with Patent Owner that any impropriety arises from Dr. Kenny's contemplation of the teachings of Nishikawa in connection with the shape of a lens for a physiological sensor. The nature of Petitioner's and Dr. Kenny's

consideration of Nishikawa is explained in cited portions of Dr. Kenny's declaration, even if Nishikawa is not listed as a third reference in the identification of the ground. *See* Ex. 1003 ¶ 87 ("[M]any prior art references of this period, such as Nishikawa (shown below) demonstrate exactly how such a lens shape [as taught by Inokawa] may be incorporated into a molded cover."); Pet. 16. Indeed, it follows readily from the Petition that a skilled artisan would have appreciated that Nishikawa's teachings provide insight as to how "the transparent acrylic material used to make Aizawa's plate can be readily formed into a lens structure as in Inokawa." Pet. 16. Nishikawa describes how its "lens unit 50" can be a transparent resin formed in the shape illustrated in Figure 6 by injection molding. Ex. 1023 ¶¶ 22, 32, 35. Dr. Kenny also explains that Nishikawa's lens shape design "is intended to provide curvature in the lens where it can do the most good and otherwise try to avoid excess use of material in order to create curvature in locations where it wouldn't do any good." Ex. 2006, 179:21–180:13.

Moreover, we observe that a rejection based on obviousness "require[s] an analysis that reads the prior art in context, taking account of 'demands known to the design community,' 'the background knowledge possessed by a person having ordinary skill in the art,' and 'the inferences and creative steps that a person of ordinary skill in the art would employ.'" *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (quoting *KSR*, 550 U.S. at 418). Furthermore, record evidence can be useful to "demonstrate the knowledge and perspective one of ordinary skill in the art." *Id.*; *see also Ariosa Diagnostics v. Verinata Health Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) ("Art can legitimately serve to document the

knowledge that skill artisan would bring to bear in reading the prior art identified as producing obviousness.”).

As noted above, Dr. Kenny makes clear that his view as to obviousness of the claims of the ’190 patent was “inspired by” or “motivated” in part by Nishikawa’s teachings as to shapes generally known to those in the art of manufacturing a lens. *See, e.g.*, Ex. 2007, 364:2–13; Ex. 2008, 73:12–21. We conclude that the record establishes that Nishikawa’s teachings are representative of background knowledge of one of ordinary skill in the art and provide context and perspective of a skilled artisan as to the type of shapes available for a convex protruding surface, such as that disclosed in Inokawa. That Dr. Kenny considered record evidence cited in the Petition as informing his view of what a skilled artisan would understand as to known types of lens shapes does not establish, in our view, any impropriety as part of that ground.

Patent Owner additionally asserts, and Dr. Madisetti testifies, that Petitioner’s combination of Aizawa and Inokawa is “problematic” because it overlooks the “small” size of Aizawa’s detectors 22 and the openings or cavities 23c in which they are housed. *See* PO Resp. 22 (citing Ex. 1006, Fig. 1(a); Ex. 2004 ¶ 63). Patent Owner, however, does not articulate what significance the size of Aizawa’s detector components have in the obviousness evaluation based on the teachings of the prior art.

We additionally do not agree with Patent Owner’s argument that Petitioner’s Reply presents new arguments and evidence that should have been first presented in the Petition. The Petition proposed a specific modification of Aizawa to include a convex protrusion in the cover, for the purpose of increasing the light gathering ability of Aizawa’s device. *See,*

e.g., Pet. 13–16. Patent Owner, in its Response, challenged that contention with several arguments that Petitioner's proposed convex protrusion would not operate in the way the Petition alleged. *See, e.g.*, PO Resp. 16–37. In its Reply, Petitioner provided arguments and evidence attempting to rebut the contentions made in the Patent Owner Response. *See* PTAB Consolidated Trial Practice Guide (Nov. 2019)[6], 73 ("A party also may submit rebuttal evidence in support of its reply."). The Reply does not change Petitioner's theory for obviousness; rather, the Reply presents more argument and evidence in support of the same theory for obviousness presented in the Petition. *Compare* Pet. 13–16, *with* Pet. Reply 2–15.

Patent Owner finally argues that a conclusion of obviousness "strains credibility" because the level of ordinary skill in the art (*see supra* Section II.C) does not require specific education or experience with optics or optical physiological monitors. *See, e.g.*, PO Resp. 32. We disagree. Concerning motivation, the record demonstrates that an ordinarily skilled artisan would have readily appreciated that: (1) Aizawa's detector 1 operates by gathering light with its photodetectors 22; (2) a lens was known to focus light on photodetectors; and (3) optical lenses may be formed by providing a convex protrusion in the lens to focus light. Indeed, Inokawa discloses such utility, function, and structure as a part of its convex lens. *See, e.g.*, Ex. 1008 ¶¶ 15, 58, Fig. 2. We are persuaded that a person of ordinary skill in the art would have understood these general concepts of optics.

Concerning reasonable expectation of success, we credit Dr. Kenny's testimony that a person of ordinary skill in the art would have understood

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[6] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

that by "positioning a lens above the optical components of Aizawa . . . the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities," and "would have found it obvious to make the protrusion portion of the LPC—namely the lens-shaped light-gathering portion—to ensure that the light-concentration effect achieved by the lens impacts all of the detectors." *See, e.g.*, Ex. 1003 ¶ 85; Ex. 2006, 179:21–180:13, 202:11–20.

Thus, we conclude that one of ordinary skill in the art would have had adequate reason to replace Aizawa's flat cover 6 with a cover comprising a convex protrusion, to improve light detection efficiency, and would have had a reasonable expectation of success in doing so.

vi. Summary

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 would have been obvious over the cited combination of references.

4. Independent Claim 26

Independent claim 26 consists of limitations that are substantially similar to elements [a]–[d] of claim 1. *Compare* Ex. 1001, 44:37–53, *with id.* at 46:22–40 (reciting a "circular housing" with a "wall"; reciting a "lens portion"). In asserting that claim 26 would have been obvious over the combined teachings of Aizawa and Inokawa, Petitioner refers to substantially the same contentions presented as to claim 1. *See* Pet. 39–41; Ex. 1003 ¶¶ 119–124.

Patent Owner does not present any argument for this claim other than those we have already considered with respect to independent claim 1. PO Resp. 12–41.

For the same reasons discussed above, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 26 would have been obvious over the cited combination of references. *See supra* II.D.3.i–v; Ex. 1003 ¶¶ 119–124.

5. Dependent Claims 2–14, 16, 17, 19–23, and 27–29

i. Dependent Claim 5

Petitioner identifies dependent claim 5 as being challenged in its proposed ground of unpatentability based on Aizawa and Inokawa. *See* Pet. 1 (listing claims 1–14, 16, 17, 19–23, 26–29 as part of this ground), 8 (heading identifying the same challenged claims). But, Petitioner does not present any contentions addressing the specific limitations of claim 5. *See id.* at 23–42 (purportedly addressing all challenged claims beyond claim 1, but failing to discuss claim 5). As such, Petitioner has not met its burden.

ii. Dependent Claims 2–4, 6–14, 16, 17, 19–23, and 27–29

Petitioner presents undisputed contentions that claims 2–4, 6–14, 16, 17, 19–23, and 27–29, which depend directly or indirectly from independent claim 1 or 26, are unpatentable over the combined teachings of Aizawa and Inokawa, and provides arguments explaining how the references teach the limitations of these claims. Pet. 23–39, 41–42; Ex. 1003 ¶¶ 88–118, 125–127.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claim 1. PO Resp. 41 ("The Petition fails to establish that independent claims 1 and 26 are obvious and thus fails to establish any of the challenged dependent claims are obvious.").

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that claims 2–4, 6–14, 16, 17, 19–23, and 27–29 would have been obvious over the combined teachings of the cited references and as supported by the testimony of Dr. Kenny.

E. Obviousness over the Combined Teachings of Aizawa, Inokawa, and Mendelson-2006

Petitioner contends that claims 23 and 24 are unpatentable based on Aizawa, Inokawa, and Mendelson-2006. Pet. 45–50. Claim 23 depends from claim 1 and recites, "[t]he noninvasive optical physiological measurement device is comprised as part of a mobile monitoring device." Ex. 1001, 46:8–11. Claim 24 depends from claim 23 and further recites, "the mobile monitoring device includes a touch-screen display." *Id.* at 46:12–14.

1. Mendelson-2006 (Ex. 1016)

Mendelson-2006 is a journal article titled "A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring," and discloses a

wireless wearable pulse oximeter connected to a personal digital assistant ("PDA"). Ex. 1016, 912.[7]

Figure 1 of Mendelson-2006 is reproduced below.

Figure 1, at top, illustrates a sensor module attached to the skin and, at bottom, presents a photograph of a disassembled sensor module and receiver module. The sensor module includes an optical transducer, a stack of round printed circuit boards, and a coin cell battery. *Id.* at 2.

[7] Petitioner cites to the native page numbering within Exhibit 1016. *See, e.g.*, Pet. 45–50. We follow Petitioner's numbering scheme.

Figure 2 of Mendelson-2006 is reproduced below.

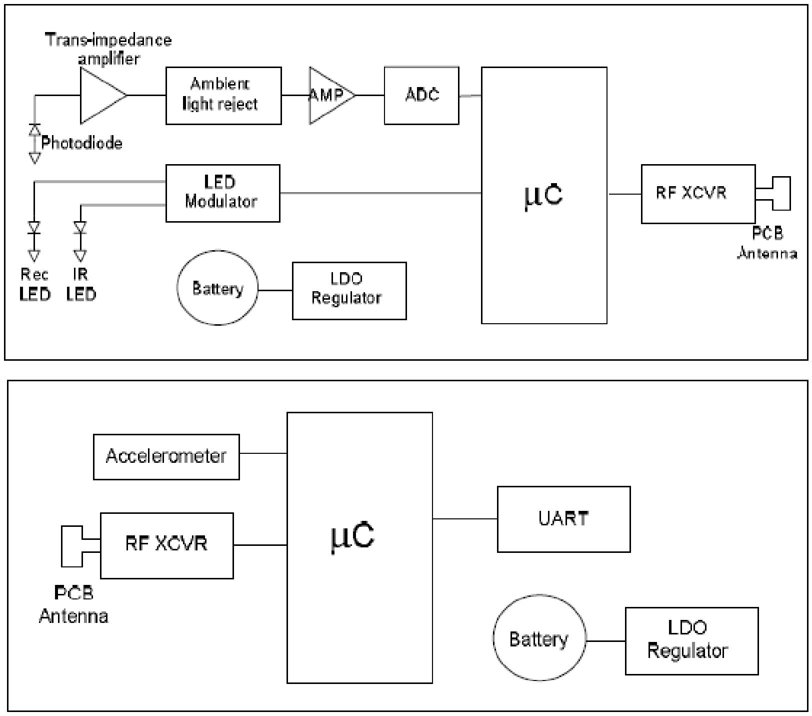


Figure 2 depicts a system block diagram of the wearable, wireless, pulse oximeter including the sensor module, at top, and the receiver module, at bottom. *Id.* The sensor module includes at least one LED, a photodetector, signal processing circuitry, an embedded microcontroller, and an RF transceiver. *Id.* at 1–2. Mendelson-2006 discloses that a concentric array of discrete photodetectors could be used to increase the amount of backscattered light detected by a reflectance type pulse oximeter sensor. *Id.* at 4. The receiver module includes an embedded microcontroller, an RF transceiver for communicating with the sensor module, and a wireless module for communicating with the PDA. *Id.* at 2.

As a PDA for use with the system, Mendelson-2006 discloses "the HP iPAQ h4150 PDA because it can support both 802.11b and Bluetooth™ wireless communication" and "has sufficient computational resources." *Id.* at 3. Mendelson-2006 further discloses that

> [t]he use of a PDA as a local terminal also provides a low-cost touch screen interface. The user-friendly touch screen of the PDA offers additional flexibility. It enables multiple controls to occupy the same physical space and the controls appear only when needed. Additionally, a touch screen reduces development cost and time, because no external hardware is required. . . . The PDA can also serve to temporarily store vital medical information received from the wearable unit.

Id.

The PDA is shown in Figure 3 of Mendelson-2006, reproduced below.

Figure 3 illustrates a sample PDA and its graphical user interface ("GUI"). *Id.* Mendelson-2006 explains that the GUI allows the user to interact with the wearable system. *Id.* "The GUI was configured to present the input and output information to the user and allows easy activation of various functions." *Id.* "The GUI also displays the subject's vital signs, activity level, body orientation, and a scrollable PPG waveform that is transmitted by the wearable device." *Id.* For example, the GUI displays numerical oxygen saturation ("SpO_2") and heart rate ("HR") values. *Id.*

2. Analysis

With support from the testimony of Dr. Kenny, Petitioner contends that claims 23 and 24 are unpatentable based on Aizawa, Inokawa, and Mendelson-2006. Pet. 45–50 (citing Ex. 1003 ¶¶ 69–71, 133–136; Ex. 1006 ¶¶ 2, 15, 23, 35; Ex. 1008 ¶ 56; Ex. 1016, 912–914, Figs. 1, 3; Ex. 1022). For instance, Petitioner applies the teachings of Mendelson-2006 to account for the mobile monitoring device features required by claim 23 and the touch-screen display recited in claim 24. *Id.*

Patent Owner does not separately address this ground, urging only that the ground "do[es] not fix the deficiencies" alleged in connection with the ground based on Aizawa and Inokawa. PO Resp. 41. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.D.

We have reviewed the Petition and its supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claims 23 and 24 are unpatentable based on Aizawa, Inokawa, and Mendelson-2006.

F. Obviousness over the Combined Teachings of Aizawa, Inokawa, Mendelson-2006, and Beyer

Petitioner contends that claim 25 is unpatentable based on Aizawa, Inokawa, Mendelson-2006, and Beyer. Pet. 56–60. Claim 25 depends from claim 1 and recites, "a processor configured to receive the one or more signals and communicate physiological measurement information to a mobile phone." Ex. 1001, 46:15–21.

1. Overview of Beyer (Ex. 1019)

Beyer is a U.S. patent titled "Cellular Phone/PDA Communication System," and discloses a "cellular PDA communication system for allowing a plurality of cellular phone users to monitor each others' location and status[and] to initiate cellular phone calls." Ex. 1019, code (57). Beyer's Figure 1 is reproduced below.

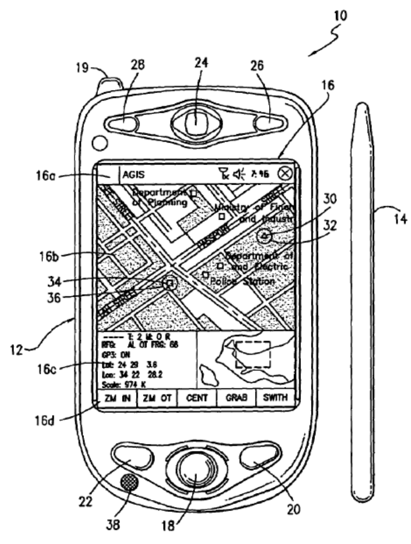


FIG. 1

Figure 1 depicts a "cellular phone/PDA and display." *Id.* at 7:8–9.

2. Analysis

With support from the testimony of Dr. Kenny, Petitioner contends that claim 25 is unpatentable based on Aizawa, Inokawa, Mendelson-2006, and Beyer. Pet. 56–60 (citing, e.g., Ex. 1003 ¶¶ 150–156; Ex. 1016, 913–914; Ex. 1019, 1:6–15, Fig. 1). For instance, Petitioner applies the teachings of Beyer to account for the processor features required by claim 25. *Id.*

Patent Owner does not separately address this ground, urging only that the ground "do[es] not fix the deficiencies" alleged in connection with the ground based on Aizawa and Inokawa. PO Resp. 41. As discussed

above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.D.

We have reviewed the Petition and its supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claim 25 is unpatentable based on Aizawa, Inokawa, Mendelson-2006, and Beyer.

G. Obviousness over the Combined Teachings of Aizawa, Inokawa, and Al-Ali

Petitioner contends that claim 5 is unpatentable over Aizawa, Inokawa, and Al-Ali. Pet. 60–62. Dependent claim 5 ultimately depends from independent claim 1 and recites that "the light permeable cover comprises a conductive layer configured to shield the at least four detectors from noise." Ex. 1001, 44:64–67.

1. Overview of Al-Ali (Ex. 1030)

Al-Ali is a U.S. patent application publication titled "Multiple Wavelength Optical Sensor." Ex. 1030, code (54). Al-Ali discloses an optical sensor with an emitter that radiates light into a tissue site to be received by a detector such that, e.g., oxygen saturation may be derived. *Id.* at code (57). Al-Ali describes detector 1900 having shield 1910 with conductive surface 1920 defining windows, shown below in Figure 19A-B. *Id.* ¶ 71.

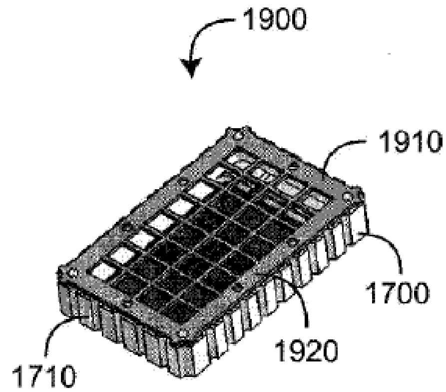


FIG. 19A

Figure 19A depicts a top view of a detector. Al-Ali explains that light is permitted to pass through the windows, while other electromagnetic noise is blocked. *Id*. Al-Ali explains that additional shielding material also can be applied to the ceramic substrate 1710. *Id.*

2. Analysis

Petitioner contends that "Al-Ali teaches shielding the detectors of a pulse oximeter/optical sensor by placing a conductive shield 1920 above the housing, thereby providing a Faraday cage that can allow 'passage of light' to the detectors while 'blocking . . . electromagnetic noise.'" *Id.* at 60 (citing Ex. 1030 ¶ 71, Fig. 19A; Ex. 1003 ¶ 156-A). Petitioner asserts this "improve[s] the sensitivity of the detectors, thereby leading to more reliable pulse/signal detection." *Id.* at 61.

According to Petitioner, a person of ordinary skill in the art "would have found it obvious to add a similar conductive shield/layer between the detectors and the LPC to prevent electromagnetic noise from reaching the detectors while still allowing desired signals/wavelengths to pass through, thereby reducing the effects of noise and resulting in improved light

collection efficiency." *Id.* (citing Ex. 1003 ¶ 156-B). Petitioner contends that this "entails the use of known solutions to improve similar systems and methods in the same way," and "would have led to [the] predictable result of reducing noise and improving signal collection without significantly altering or hindering the functions performed by Aizawa." *Id.* at 62 (citing Ex. 1003 ¶ 156-C).

Patent Owner does not separately address this ground, urging only that the ground "do[es] not fix the deficiencies" alleged in connection with the ground based on Aizawa and Inokawa. PO Resp. 41. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.D.

We have reviewed the Petition and its supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claim 5 is unpatentable based on Aizawa, Inokawa, and Al-Ali. Specifically, Al-Ali teaches the use of a conductive material to eliminate noise. Ex. 1030 ¶ 71. In light of this teaching, we credit Dr. Kenny's unrebutted testimony that a person of ordinary skill in the art would have found it obvious to implement such a conductive material in the sensor of Aizawa and Inokawa to reduce noise, as was well-known in the art. Ex. 1003 ¶¶ 156-A, 156-B.

H. Obviousness over the Combined Teachings of Aizawa, Inokawa, and Ohsaki

Petitioner contends that claims 1–14, 16, 17, 19–23, and 26–29 are unpatentable over Aizawa, Inokawa, and Ohsaki. Pet. 42–45.

Because we have already determined that these claims are unpatentable based on Aizawa and Inokawa, which is dispositive as to these challenged claims, we need not reach this additional ground applied to these

claims. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) ("[T]he Board need not address issues that are not necessary to the resolution of the proceeding.").

I. Obviousness over the Combined Teachings of Aizawa, Inokawa, Goldsmith, and Lo

Petitioner contends that claims 23–25 are unpatentable over Aizawa, Inokawa, Goldsmith, and Lo. Pet. 51–56.

Because we have already determined that these claims are unpatentable based on Aizawa, Inokawa, and Mendelson-2006 (claims 23–24) or Mendelson-2006 and Beyer (claim 25), we need not reach this additional ground applied to these claims. *See SAS Inst.*, 138 S. Ct. at 1359; *Boston Sci.*, 809 F. App'x at 990.

J. Obviousness over the Combined Teachings of Mendelson-1988 and Inokawa

Petitioner contends that claims 1–14, 16–22, and 26–30 of the '190 patent would have been obvious over the combined teachings of Mendelson-1988 and Inokawa. Pet. 62–94.

1. Overview of Mendelson-1988 (Ex. 1015)

Mendelson-1988 discloses a pulse oximeter, with an optical reflectance sensor suitable for noninvasive monitoring of a user's arterial hemoglobin oxygen saturation (SpO_2), via the user's forehead. *See* Ex. 1015, 167 (title & abstract).

Figure 2 is reproduced below:

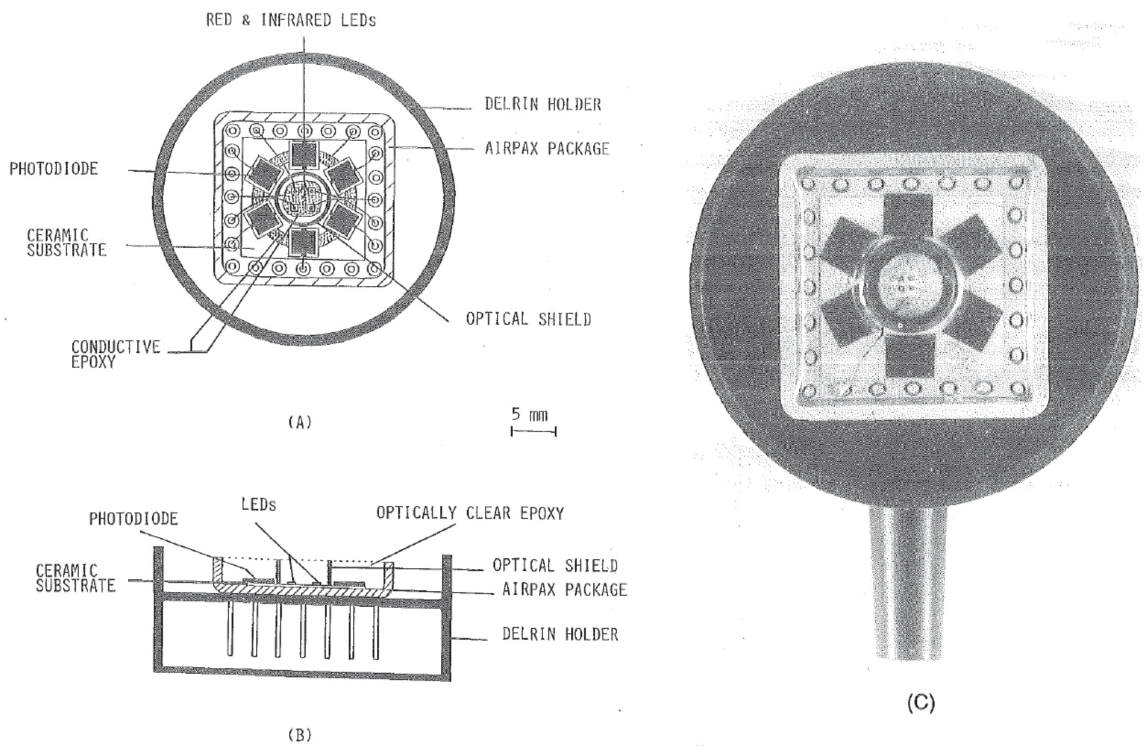


Figure 2 illustrates the sensor of Mendelson-1988, including: (A) a top view diagram; (B) a side view diagram; and (C) a photograph. *Id.* at 169.

The sensor includes two red LEDs and two infrared LEDs for emitting light into the user's tissue, and six photodiodes "arranged symmetrically in a hexagonal configuration" surrounding the four emitters, to detect light reflected back to the sensor from the user's tissue. *Id.* at 168 ("SENSOR DESIGN"). The user's "SpO_2 can be calculated from the ratio of the reflected red and infrared photoplethysmograms." *Id.* at 167. "To minimize the amount of light transmission and reflection between the LEDs and the photodiodes within the sensor, a ring-shaped, optically opaque shield of black Delrin . . . was placed between the LEDs and the photodiode chips." *Id.* at 168 (col. 2). "The optical components were encapsulated inside the

package using optically clear adhesive." *Id.* "The microelectronic package was mounted inside a black Delrin housing." *Id.*

2. *Independent Claim 1*

Petitioner contends that claim 1 would have been obvious over the combined teachings of Mendelson-1988 and Inokawa. Pet. 63–67 (combination), 68–75 (claim 1).

i. *"A noninvasive optical physiological measurement device adapted to be worn by a wearer, the noninvasive optical physiological measurement device providing an indication of a physiological parameter of the wearer comprising"*

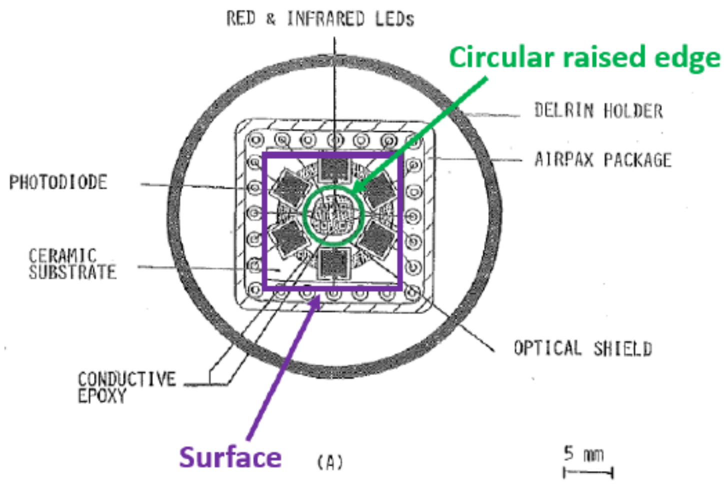
The cited evidence supports Petitioner's undisputed contention that Mendelson-1988 discloses a noninvasive optical physiological measurement device, i.e., an "optical reflectance sensor" that monitors "arterial hemoglobin oxygen saturation," a physiological parameter of the wearer. Pet. 68; *see, e.g.*, Ex. 1015, code (57), 167, 172; Ex. 1003 ¶ 157.

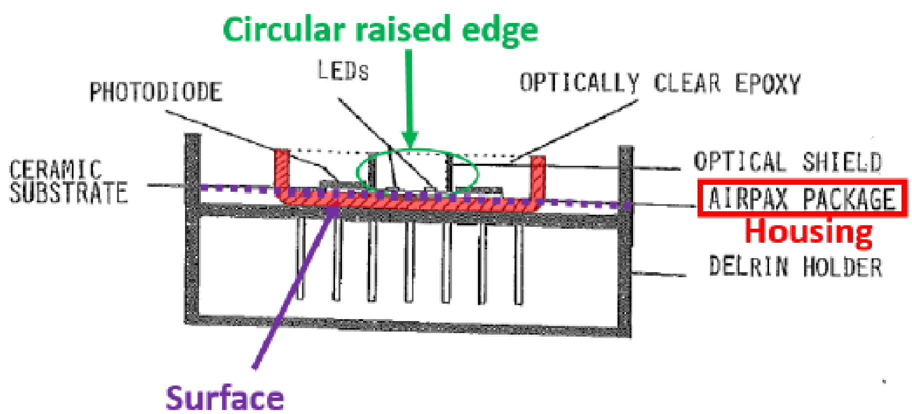
ii. *"[a] one or more light emitters"*

The cited evidence supports Petitioner's undisputed contention that Mendelson-1988 discloses two red LEDs and two infrared LEDs. Pet. 68; *see, e.g.*, Ex. 1015, 168 ("The optical reflectance sensor used in this study consists of two red (peak emission wavelength: 660 nm) and two infrared (peak emission wavelength: 930 nm) LED chips.")), Fig. 2(a); Ex. 1003 ¶ 158.

iii. "[b] a housing having a surface and a circular raised edge extending from the surface"

The cited evidence supports Petitioner's undisputed contention that Mendelson-1988 discloses an AIRPAX package, i.e., a housing with a ceramic substrate, i.e., a surface, and a circular raised edge extending from the surface. Pet. 69. Petitioner's annotated versions of Mendelson-1988's Figures 2A and 2B are reproduced below.





Pet. 69–70. The modified figures depict top and side views of Mendelson-1988's sensor with a housing (depicted in red) having a surface (depicted in

purple) with a circular raised edge (depicted in green) extending from the surface. *Id.*; Ex. 1003 ¶ 159.[8]

> iv. *"[c] at least four detectors arranged on the surface and spaced apart from each other, the at least four detectors configured to output one or more signals responsive to light from the one or more light emitters attenuated by body tissue, the one or more signals indicative of a physiological parameter of the wearer"*

The cited evidence supports Petitioner's undisputed contention that Mendelson-1998 discloses "six silicon photodiodes . . . arranged symmetrically in a hexagonal configuration" on the surface. Pet. 69, 72; *see, e.g.*, Ex. 1015, 168, Figs. 2(A)–(B). Mendelson-1998 discloses that the photodiodes output "current pulses" indicative of a physiological parameter of the wearer in response to light emitted by the emitters and reflected from the skin. Pet. 72–73; *see, e.g.*, Ex. 1015, 167 ("SpO_2 can be calculated from the ratio of the reflected red and infrared photoplethysmograms."); Ex. 1003 ¶ 163.

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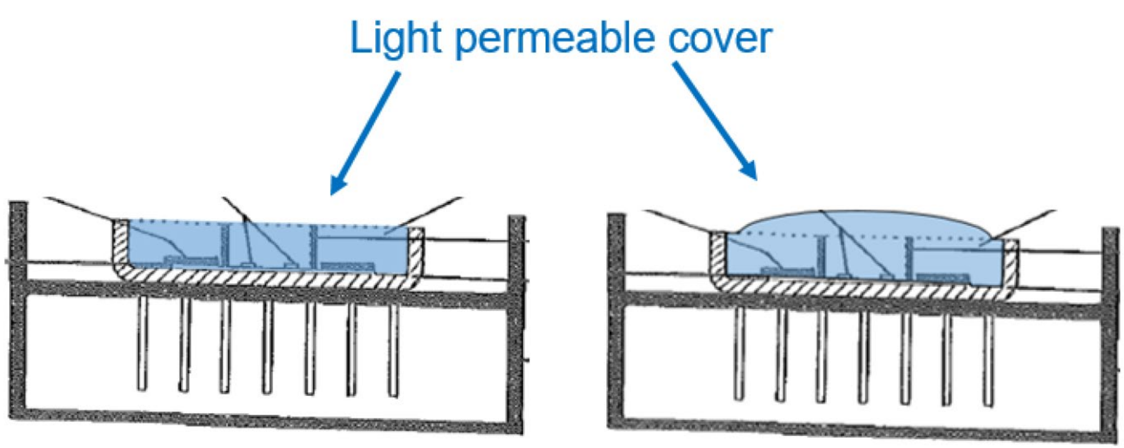
[8] Petitioner also alleges that, "[a]lternatively, the outer wall of the AIRPAX microelectronic package (housing), as indicated below, can be modified to be a circular raised edge extending from the surface." Pet. 70–72 (emphasis omitted). We do not rely on this alternative contention regarding claim 1.

> v. *"[d] a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors."*

<u>Petitioner's Contentions</u>

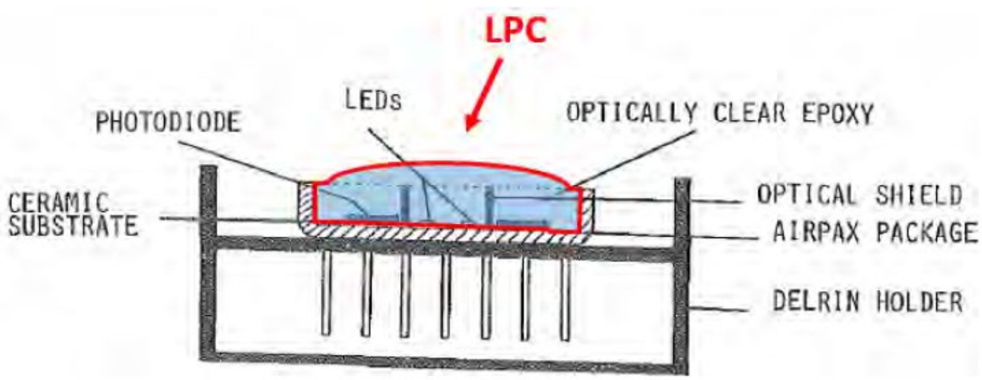
Petitioner contends that Mendelson-1988's sensor discloses all limitations of claim 1, except that its light permeable cover, i.e., the "OPTICALLY CLEAR EPOXY" in Figure 2B, which is arranged above a portion of the housing and covers the detectors, lacks the claimed "protrusion." *See* Pet. 73–75; Ex. 1003 ¶¶ 165–171. As discussed above in Section II.D.3, Petitioner contends that Inokawa's sensor includes lens 27, comprising a convex protrusion arranged to cover its light detector 25. Pet. 65. Petitioner reasons that an ordinarily skilled artisan would have been motivated, with a reasonable expectation of success, to modify Mendelson-1988's optical SpO_2 sensor, in light of Inokawa's optical pulse sensor, by adding a lens with a protrusion to Mendelson-1988's cover to improve the sensor's light detection efficiency. *Id.* at 66.

Dr. Kenny provides the following illustrations to portray the proposed modification of Mendelson-1988's sensor (Ex. 1003 ¶ 168):

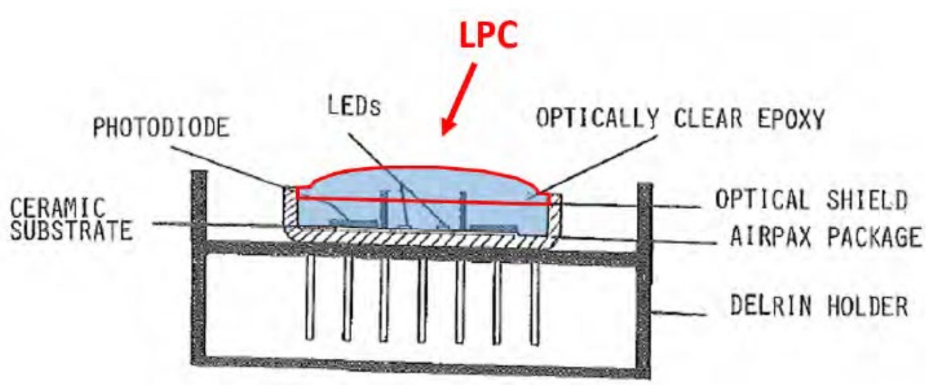


At the left, Dr. Kenny has excerpted and annotated Mendelson-1988's Figure 2B, to identify the pre-existing cover (colored blue) which covers the light emitters and detectors. *See id.* At the right, Dr. Kenny has illustrated the device resulting from the proposed modification of the cover to have a protrusion (also colored blue). *See id.*

Petitioner further asserts "there are two alternative ways of mapping the claimed 'light permeable cover,' or LPC, to the modified cover above." Pet. 74; Ex. 1003 ¶¶ 172–173. Dr. Kenny provides the following two annotations of Mendelson-1988's Figure 2B to identify these alternative mappings:



APPLE-1015, FIG. 2(B)



APPLE-1015, FIG. 2(B).

Dr. Kenny's first mapping (top figure) equates the cover to the entire depth of the epoxy contained within the AIRPAX package as shown in red outline. Ex. 1003 ¶ 172. Dr. Kenny's second mapping (bottom figure) equates the cover to a partial depth of the epoxy within the package as shown in red outline. *Id.* ¶ 173 ("[A person of ordinary skill in the art] would have been able to use the top portion of the housing . . ., as in Nishikawa, to help form the LPC portion on top of the sealing portion.").

Petitioner adds that a person of ordinary skill in the art "would have realized that the epoxy layer [of Mendelson-1998] could have been given a shape that would help further advance Mendelson-1988's objective of improving detection efficiency," "requir[ing] only routine knowledge of sensor design and assembly." Pet. 64, 66 (citing Ex. 1015, 168, 173); Ex. 1003 ¶¶ 165, 169. For example, "as demonstrated by Nishikawa, molding clear epoxy, as in Mendelson-1988, into a lens was well understood." Pet. 66–67 (citing Ex. 1023, Fig. 6, ¶¶ 22, 32, 35, 37; Ex. 1003 ¶ 170).

Patent Owner's Arguments

Patent Owner is of the view that Petitioner has not met its burden to demonstrate the obviousness of modifying Mendelson-1988's sensor to have a protrusion, based on substantially the same analysis and testimony discussed above in the context of combining Aizawa and Inokawa. *See* PO Resp. 43–46; Ex. 2004 ¶¶ 94–100; *supra* Section II.D.3. For example, Mendelson-1988, like Aizawa, provides a central emitter or emitters surrounded by several detectors. *Compare* Ex. 1015, 169 (Fig. 2) (showing four central LEDs surrounded by six photodiodes), *with* Ex. 1006,

Figs. 1(a)–1(b) (showing one central LED 21 surrounded by four photodetectors 22).

Patent Owner argues that Mendelson-1988 discloses only that it encapsulates its electronic components with a flat optically clear adhesive/epoxy, which is not a "cover." PO Resp. 46 (citing Ex. 1004 ¶¶ 102–103). Patent Owner contends that the '190 patent distinguishes between resin and covers. PO Resp. 47 (citing Ex. 1001, 36:37–46). Patent Owner also argues that Nishikawa, on which Petitioner relies, "never mentions a cover, and instead discusses encapsulation of components using an integrally molded resin." *Id.* (citing Ex. 1023 ¶ 35). Likewise, Patent Owner characterizes Inokawa's cover as a "***distinct structure***, not an undifferentiated mass of resin on a surface." *Id.* (citing Ex. 1008 ¶ 103).

Patent Owner also objects to Petitioner's alternative mapping, providing for a cover with a protrusion to be found in two different ways. *See* PO Resp. 46–49; Ex. 2004 ¶¶ 102–107. This alternative mapping, in according to Patent Owner, is "ambiguous[]," and the second mapping incorporates an "arbitrary" line drawn to define the bottom of the cover in "an ***undifferentiated*** mass of material." PO Resp. 48–49. Patent Owner also argues that "Petitioner's inability to consistently identify a 'cover' reveals the hindsight-driven nature of its arguments." *Id.* at 49.

<u>Petitioner's Reply</u>

Petitioner maintains that the Petition and supporting testimony adequately account for the "cover" required by the claims of the '190 patent, including the "alternative mapping" configuration. Pet. Reply 22.

Patent Owner's Sur-reply

Patent Owner's Sur-reply generally reiterates its arguments challenging Petitioner's contentions. PO Sur-reply 18–20.

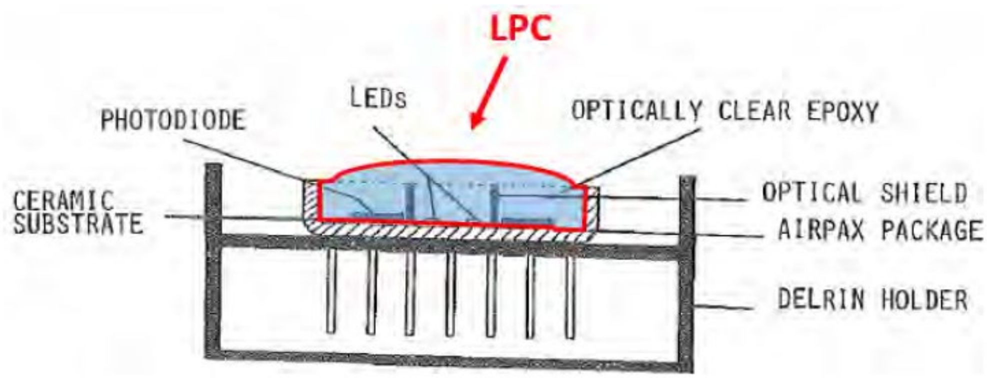
Analysis

As an initial matter, we find that a preponderance of the evidence establishes that the Mendelson-1988 sensor's optically clear epoxy is a light permeable cover that is arranged above a portion of the housing and covers the sensor's detectors. In particular, it is clear from Figures 2A and 2B that the epoxy extends from the top of the sensor at the dotted line in the figure, down into the well of the AIRPAX package, to cover all four LEDs and all six photodiodes disposed at the bottom of the well. *See also* Ex. 1015, 168 ("The optical components were encapsulated inside the package using optically clear adhesive."). Although Patent Owner disagrees, its position is premised on its proposed claim construction of the term "cover" as excluding resins and epoxies. *See* PO Resp. 46–48. For reasons provided in Section II.A.1 above, we do not find that claim construction persuasive, and Patent Owner does not distinguish Mendelson-1988 from claim 1 on this basis.

Thus, we determine that Petitioner has established persuasively that Mendelson-1988's sensor teaches every limitation of claim 1, except that its light permeable cover has a flat surface and, thus, does not include a "protrusion." We, however, conclude that a preponderance of the evidence supports Petitioner's contention that it would have been obvious to modify the top surface of Mendelson-1988's cover to include a protrusion, in order to increase the amount of backscattered light received by Mendelson-1988's peripheral detectors. Our reasoning is substantially identical to the analysis

provided above in connection with the ground based on Aizawa and Inokawa, with Mendelson-1988 replacing Aizawa in the combination. *See supra* Section II.D.3. Patent Owner does not cite, and we do not discern, any material difference between Mendelson-1988 and Aizawa that might lead to a different result here, with one possible exception.

That difference is Petitioner's alternative mapping of the claimed "cover" in the proposed modification of Mendelson-1988. We rely on the first mapping, but not the second, to decide in Petitioner's favor. Petitioner's first mapping is again reproduced here (Ex. 1003 ¶ 172):



APPLE-1015, FIG. 2(B)

In this modified and annotated version of Figure 2B of Mendelson-1988, Dr. Kenny identifies how Mendelson-1988's light permeable cover may be modified to have a protrusion, wherein the modified cover (colored blue) includes the entire depth of the optically clear epoxy contained within the AIRPAX package (outlined red). *Id.*; Pet. 74. Patent Owner objects to this mapping as ambiguous, but we determine Dr. Kenny's annotations reproduced above are sufficiently clear to establish obviousness by a preponderance of the evidence.

vi. Summary

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 would have been obvious over the cited combination of references.

3. Independent Claim 26

Independent claim 26 consists of limitations that are substantially similar to elements [a]–[d] of claim 1. *Compare* Ex. 1001, 44:37–53, *with id.* at 46:22–40 (reciting a "circular housing" with a "wall"; reciting a "lens portion . . . in optical communication with the . . . detectors"). In asserting that claim 26 would have been obvious over the combined teachings of Mendelson-1988 and Inokawa, Petitioner refers to many of the same contentions presented as to claim 1. *See* Pet. 88–91; Ex. 1003 ¶¶ 206–212.

We address the parties' contentions to the extent they vary or expand upon those discussed above. We do not address contentions that we have already considered with respect to independent claim 1.

With respect to the limitation reciting "a lens portion . . . comprising a protrusion in optical communication with the at least four detectors," Petitioner additionally contends that "because reflected light received by Mendelson-1988's six detectors passes through the protruded lens portion as provided by Inokawa, the lens/protrusion is in optical communication with the detectors." Pet. 91. We agree. As discussed in Section II.J.2.v, we are persuaded that an ordinarily skilled artisan would have been motivated, with a reasonable expectation of success, to modify Mendelson-1988's sensor, in light of Inokawa's sensor, by adding a protruding lens to Mendelson-1988's cover to improve the sensor's light detection efficiency. *See, e.g.*, Pet. 66. In the proposed modification, emitted and reflected light passes through the

added lens/protrusion, taught by Inokawa, before reaching the detectors. Ex. 1003 ¶ 211. As such, we agree that it is "in optical communication," as claimed.

With respect to the limitation reciting "a circular housing comprising a surface and a wall protruding from the surface," Petitioner contends that "[a]lthough the housing [of Mendelson-1998] appears to have a square shape, not a circular one, a [person of ordinary skill in the art] would have recognized that microelectronic packaging as used in Mendelson-1988 comes in various shapes and sizes," and that such an artisan "would have considered using a differently shaped housing, namely a circular one, to be obvious" because a circular housing with a circular wall was well known and the shape would have imparted nothing new or inventive. Pet. 89–90 (citing, e.g., Ex. 1003 ¶¶ 206–209). For example, Petitioner relies on Mendelson-799,[9] which discloses a sensor for an optical measurement device having a circular shape. *Id.* (citing Ex. 1025, Fig. 7, 9:34–36).

Patent Owner argues that Mendelson-1988 and Inokawa provide square housings for their components. PO Resp. 52. According to Patent Owner, "Petition never identifies a motivation to pick a circular-shaped housing instead of the existing square shape" and that a skilled artisan would not have made such a modification without some perceived benefit for doing so. *Id.* at 53 (citing, e.g., Ex. 2004 ¶ 114). Patent Owner objects to Petitioner's reliance on the sensor shape taught by Mendelson-799 because (1) Mendelson-799 is not included in any ground, and (2) Mendelson-799

[9] U.S. Patent No. 6,801,799 B2, filed Feb. 6, 2003, issued Oct. 5, 2004 ("Mendelson-799," Ex. 1025).

does not disclose a cover and, as such, "cannot disclose a circular housing and a cover of the circular housing, as claim 26 requires." *Id.*

In its Reply, Petitioner contends that "neither the '190 patent nor [Patent Owner] provides any explanation of how the particular housing shape solves some problem or presents some unexpected result." Pet. Reply 24.

In its Sur-reply, Patent Owner reiterates its positions from its Response. PO Sur-reply 21.

We are persuaded by Petitioner's contentions. As discussed in Section II.J.2.iii, Mendelson-1988 discloses a housing in the form of an AIRPAX package that has a square shape when viewed from above. *See* Ex. 1015, Fig. 2(A). Petitioner's and Dr. Kenny's general assessment that a person of ordinary skill in the art would have understood that a circular housing shape was a known option for housing components of a physiological sensor finds support in the record. Pet. 88–90; Ex. 1003 ¶¶ 208–209. In that respect, although Mendelson-799 was not listed in the styling of the proposed grounds of unpatentability, its teachings plainly were offered in the Petition as evidence of the background knowledge that an ordinarily skilled artisan would have brought to bear in an evaluation of the teachings of Mendelson-1988 and Inokawa. Pet. 88–90. Moreover, it is clear that Patent Owner understood that the proposed ground offered in the Petition considered the disclosure of Mendelson-799, and Patent Owner had opportunity to address that disclosure. Indeed, Patent Owner availed itself of that opportunity during trial (*see, e.g.*, PO Resp. 53; PO Sur-reply 21).

We further find unavailing Patent Owner's argument that "Mendelson[-799] does not disclose a cover (or even epoxy encapsulation)

and thus cannot disclose a circular housing and a cover of the circular housing, as claim 26 requires." PO Resp. 53. Figure 7 of Mendelson-799 is reproduced below:

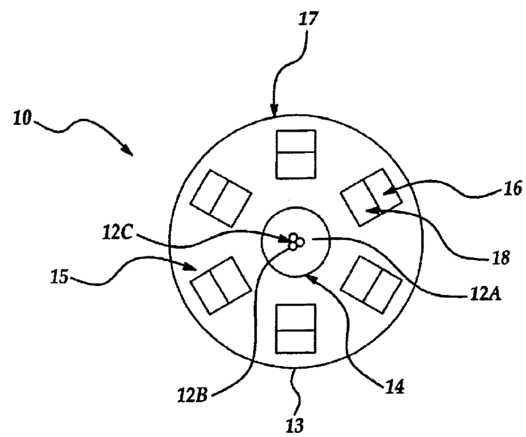


Figure 7

Figure 7 is a top view of optical sensor 10 comprising light source 12 composed of three LEDs 12A, 12B, and 12C emitting light of three different wavelengths, and an array of six near detectors 18 and six far detectors 16 "arranged in two concentric ring-like arrangements" surrounding light source 12. Ex. 1025, 9:23–34. "All these elements are accommodated in a sensor housing 17" which, as can be seen in Figure 7, is clearly circular. *Id.* at 9:34–35. Patent Owner does not articulate why the presence or absence of a cover in Mendelson-799 somehow serves to discount the unambiguous presentation of a sensor housing having a circular shape.

Furthermore, one of ordinary skill in the art would have understood that the AIRPAX package of Mendelson-1988 and the housing 17 of Mendelson-799 are performing the same function of enclosing a central collection of light emitters which are surrounded by an array of light detectors in an optical sensor attached to a user's body. *See, e.g.*, Ex. 1015, Figs. 2A–2B; Ex. 1025, Fig. 7. The evidence of record also does not suggest that the shape of such a housing has any functional significance in the

operation of the optical sensor, or that any particular shape was preferred or restricted. Thus, the evidence suggests that a square shape and a circular shape of such a housing were known in the art to be predictable substitutes for one another, and therefore obvious variants. *See, e.g.*, *KSR*, 550 U.S. at 416 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result."); *id.* at 417 ("[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." (citation omitted)).

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 26 would have been obvious over the cited combination of references.

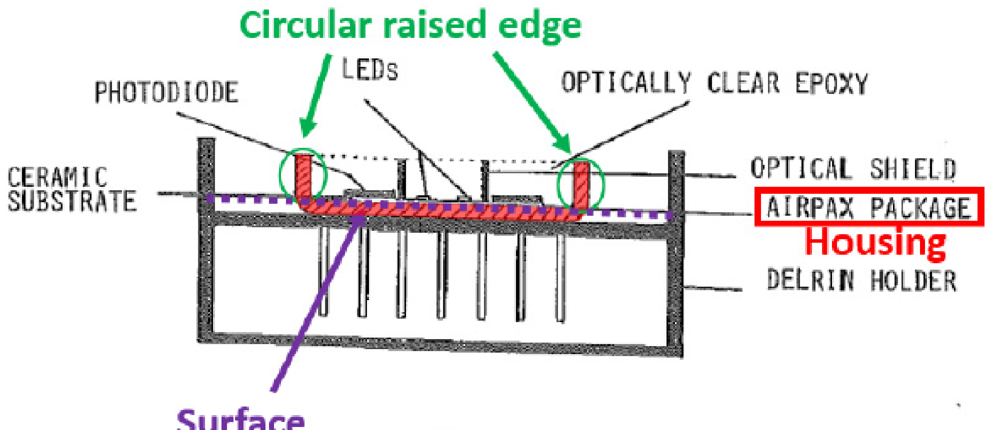
4. Dependent Claims 2–14, 16–22, and 27–30

i. Dependent Claim 3

Dependent claim 3 recites that "the circular raised edge creates a gap between the surface and the light permeable cover." Ex. 1001, 44:58–60.

For this claim, Petitioner relies upon a different mapping of the "circular raised edge" than that primarily relied upon in claim 1. *See supra* § II.J.2.iii, n.8 (identifying, but not relying upon, Petitioner's alternate mapping). Specifically, Petitioner contends that although Mendelson-1988's sensor presents a square shape, it would have been obvious to a skilled artisan that a circular shape, and circular raised edge, could have been used. Pet. 71; *see also supra* § II.J.3 (similar arguments regarding claim 26).

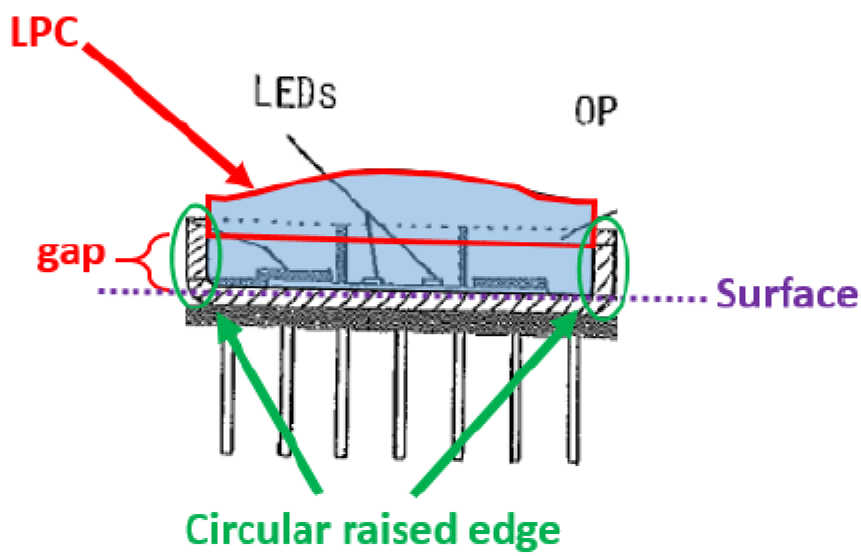
Petitioner presents an annotated version of Mendelson-1988's Figure 2(B) below.



(B)

The annotated figure identifies an outer edge of Mendelson-1988's AIRPAX package with the label "Circular raised edge." Pet. 71; Ex. 1003 ¶ 160.

Regarding claim 3, Petitioner contends that, in the modified sensor of Mendelson-1988 and Inokawa, "the [light permeable cover] portion is separated from the surface by a gap," as shown below. Pet. 76.



The annotated and modified figure above presents Mendelson-1988's sensor with the epoxy formed to extend from the bottom surface upward through a protruding cover, and with a line identifying the upper portion of the epoxy

that Petitioner contends is the light permeable cover. Thus, according to Petitioner, "[t]he size of the gap above is defined, in part, by the raised edge of the housing, which as described above for [1b] can be circular, that surrounds the epoxy structure and serves as a mold that define its overall height (and thus the size of the gap)." Pet. 77 (citing Ex. 1023 ¶¶ 34–38, Figs. 5–6; Ex. 1003 ¶¶ 178–179).

In response, Patent Owner argues that "drawing an arbitrary line through an undifferentiated mass of material does not create a 'gap,'" and characterizes Petitioner's alternate mappings as ambiguous. PO Resp. 49 (citing Ex. 2004 ¶¶ 108–109; Ex. 2007, 355:12–359:5). Patent Owner argues that the term "gap" requires some kind of "break," which is absent in the proposed combination. *Id.* (citing Ex. 1001, 36:24–28; Ex. 1017; Ex. 2004 ¶ 110). Moreover, Patent Owner argues that in this mapping, it is not the circular raised edge that "creates" the gap, as claimed. *Id.* at 51.

In its Reply, Petitioner contends that "the 'line' between the LPC/cover and the epoxy encapsulation layer underneath is not arbitrary, instead being formed, for instance, by a common manufacturing technique for creating epoxy lenses in which the epoxy lens layer is provided on top of a separately formed epoxy encapsulation layer." Pet. Reply 23–24 (citing Ex. 1003 ¶¶ 178–179; Ex. 1047 ¶ 49).

In its Sur-reply, Patent Owner argues that Petitioner's reliance on Nishikawa for teachings of how to manufacture separate epoxy layers is unavailing because Nishikawa's process seeks to avoid any gaps in the epoxy. PO Sur-reply 21 (citing Pet. 67).

Upon review of the foregoing, we conclude Petitioner's case for the obviousness of claim 3 falls short. Petitioner's identification of the bottom

border of the LPC "cover" in this mapping is arbitrary, and is not supported by a preponderance of the evidence. Dr. Kenny does not provide any persuasive reasoning in support of his identification of the "cover" as terminating at the bottom border he has identified, when the same mass of epoxy extends further beyond that border to the surface of the sensor. *See* Ex. 1003 ¶¶ 90–91. We perceive no such reasoning, apart from impermissible hindsight.

Dr. Kenny testifies that "the height of the 'circular wall' in Mendelson-1988 necessarily impacts the position of the LPC (cover), in turn necessarily impacting the size of the 'gap' between the cover and the surface," and, as such, the "line" between the cover and epoxy underneath is not arbitrary. Ex. 1047 ¶ 49; *see also* Ex. 1003 ¶ 90. Instead, Dr. Kenny asserts, this represents a common manufacturing technique to form separate layers of epoxy, for example, as taught by Nishikawa. Ex. 1047 ¶ 49 (citing Ex. 1023 ¶¶ 34–38, Figs. 5–6).

But we find this testimony deficient in two primary ways. First, Dr. Kenny's reliance on Nishikawa is misplaced. Dr. Kenny relies on Nishikawa's disclosure that sealing portion 40 and lens unit 50 may be formed in separate injection molding steps, leading to a defined border between them which is shown as a horizontal line in Nishikawa's Figure 6. Ex. 1023 ¶¶ 34–35. Thus, Nishikawa *does* establish, as Dr. Kenny testifies, that Mendelson-1988's epoxy layer *could* have been formed in a two-step injection molding process, leading to a border between two layers of epoxy. However, Dr. Kenny errs in "focus[ing] on what a skilled artisan would have been *able* to do, rather than what a skilled artisan would have been *motivated* to do." *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056,

1068–69 (Fed. Cir. 2018) (citing *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014)). Dr. Kenny does not provide any persuasive motivation for using Nishikawa's two-step molding process within the context of Mendelson-1988's sensor. Thus, we conclude Dr. Kenny "succumbed to hindsight bias in [his] obviousness analysis." *InTouch*, 751 F.3d at 1352.

Second, Dr. Kenny's testimony that the height of the circular wall impacts the position of the cover is belied by Dr. Kenny's illustration of the proposed modification in which the "line" dividing the cover from the epoxy is located *below* the full height of the circular wall. *See* Ex. 1047 ¶ 48. Thus, in no way does the AIRPAX package wall create the gap. Instead, the identified "gap" (to the extent it can be named as such) is created by the height of the lower layer of epoxy purportedly laid down in Nishikawa's first injection molding step.

For the foregoing reasons, we conclude Petitioner has not demonstrated by a preponderance of the evidence that claim 3 is unpatentable over Mendelson-1988 and Inokawa. Dependent claims 6–14 and 16 depend further from claim 3 and, as such, Petitioner's contentions with respect to those claims also fail.

ii. Dependent Claim 5

Petitioner identifies dependent claim 5 as being challenged in its proposed ground of unpatentability based on Mendelson-1988 and Inokawa. *See* Pet. 2 (listing claims 1–14, 16–22, and 26–30 as part of this ground), 62 (heading identifying the same challenged claims). But, Petitioner does not present any contentions addressing the specific limitations of claim 5. *See*

id. at 75–94 (purportedly addressing all challenged claims beyond claim 1). As such, Petitioner has not met its burden.

iii. Dependent Claims 2, 4, 17–22, and 27–30

Petitioner presents undisputed contentions that claims 2, 4, 17–22, and 27–30, which depend directly or indirectly from independent claim 1 or 26, are unpatentable over the combined teachings of Mendelson-1988 and Inokawa, and provides arguments explaining how the references teach the limitations of these claims. Pet. 75–78, 84–87, 91–94; Ex. 1003 ¶¶ 174–175, 180, 198–203, 213–219.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claims 1 and 26. PO Resp. 57 ("The Petition fails to establish that independent claims 1 and 26 are obvious over the cited references of Ground 2A and therefore fails to establish obviousness of any of the challenged dependent claims.").

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that claims 2, 4, 17–22, and 27–30 would have been obvious over the combined teachings of the cited references and as supported by the testimony of Dr. Kenny.

K. Obviousness over the Combined Teachings of Mendelson-1988, Inokawa, and Mendelson-2006

With support from the testimony of Dr. Kenny, Petitioner contends that claims 23 and 24 would have been obvious over the combined teachings of Mendelson-1988, Inokawa, and Mendelson-2006. Pet. 94–97 (citing

Ex. 1003 ¶¶ 220–224; Ex. 1008 ¶ 56; Ex. 1015, 167, 171, Fig. 2; Ex. 1016, 912–915, Figs. 1–3; Ex. 1022). For instance, Petitioner applies the teachings of Mendelson-2006 to account for the mobile monitoring device features required by claim 23 and the touch-screen display recited in claim 24. *Id.*

Patent Owner does not separately address this ground, urging only that the ground "do[es] not fix the Petition's deficiencies" alleged in connection with the ground based on Mendelson-1988 and Inokawa. PO Resp. 57. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.J.

We have reviewed the Petition and its supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claims 23 and 24 are unpatentable based on Mendelson-1988, Inokawa, and Mendelson-2006.

L. Obviousness over the Combined Teachings of Mendelson-1988, Inokawa, Mendelson-2006, and Beyer

With support from the testimony of Dr. Kenny, Petitioner contends that claim 25 would have been obvious over the combined teachings of Mendelson-1988, Inokawa, Mendelson-2006, and Beyer. Pet. 97–99 (citing, e.g., Ex. 1003 ¶¶ 224–231; Ex. 1016, 913–914; Ex. 1019, 1:6–15, Fig. 1). For instance, Petitioner applies the teachings of Beyer to account for the processor features required by claim 25. *Id.*

Patent Owner does not separately address this ground, urging only that the ground "do[es] not fix the Petition's deficiencies" alleged in connection with the ground based on Mendelson-1988 and Inokawa. PO Resp. 57. As discussed above, we do not agree with Patent Owner as to any such deficiencies. *See supra* § II.J.

We have reviewed the Petition and its supporting evidence and conclude that Petitioner has shown by a preponderance of the evidence that claim 25 is unpatentable based on Mendelson-1988, Inokawa, Mendelson-2006, and Beyer.

III. CONCLUSION

In summary:[10]

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–14, 16, 17, 19–23, 26–29	103	Aizawa, Inokawa	1–14, 16, 17, 19–23, 26–29	5
23, 24	103	Aizawa, Inokawa, Mendelson-2006	23, 24	
25	103	Aizawa, Inokawa, Mendelson-2006, Beyer	25	
5	103	Aizawa, Inokawa, Al-Ali	5	

[10] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

23–25	103[11]	Aizawa, Inokawa, Goldsmith, Lo		
1–14, 16, 17, 19–23, 26–29	103[12]	Aizawa, Inokawa, Ohsaki		
1–14, 16–22, 26–30	103	Mendelson-1988, Inokawa	1, 2, 4, 5, 17–22, 26–30	3, 5–14, 16
23, 24	103	Mendelson-1988, Inokawa, Mendelson-2006	23, 24	
25	103	Mendelson-1988, Inokawa, Mendelson-2006, Beyer	25	
Overall Outcome			1–14, 16–30	

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1–14 and 16–30 of the ’190 patent have been shown to be unpatentable; and

[11] As explained above, because we conclude that the challenged claims are unpatentable on other grounds, we do not reach the merits of this ground.
[13] As explained above, because we conclude that the challenged claims are unpatentable on other grounds, we do not reach the merits of this ground.

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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CERTIFICATE OF SERVICE

I hereby certify that the original of this Notice of Appeal was filed via U.S.P.S. Priority Mail Express on July 27, 2022 with the Director of the United States Patent and Trademark Office at the address below:

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United States Patent and Trademark Office
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A copy of this Notice of Appeal is being filed and served on July 27, 2022 as follows:

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